

The synchronisation of primary healthcare



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'Here's your beetle.'

Carl Gustav Jung, holding out a beetle that had flown in through the window to a patient who was recounting a dream featuring a golden beetle.

The Swiss analytical psychiatrist Jung defined synchronicity as the simultaneous occurrence of two events linked by meaning, but not by causality¹.

Since 1978, the concept of primary health care has been redefined on several occasions. The term itself has various forms in the French language, such as 'soins premiers' in France or 'soins de première ligne' in Switzerland. In 2025, the World Health Organisation proposed the following definition: "*an approach to health that takes account of society as a whole, aimed at ensuring the highest possible level of health and well-being and its equitable distribution, by prioritising the needs of populations as early as possible throughout the continuum of care—ranging from health promotion and disease prevention to treatment, rehabilitation and palliative care—and by remaining as close as possible to people's everyday lives*"².

In France, several disciplines within primary healthcare have undergone a process of integration into the university system following the 1999 Bologna Declaration. This declaration sought to harmonise higher education systems (Bachelor's, Master's and Doctorate degrees) across 48 countries, including France. This transition towards university-based education has affected training programmes for paramedical professions. For example, nursing education was aligned with the Bachelors degree structure in 2009 while midwifery training intergated at a Master's level in 2019. Following these initial steps, the move towards university-based education has continued with the creation of dedicated health sections of the National Council of Universities (CNU): including section 91 for rehabilitation sciences and section 92 for nursing sciences. These changes enabled the recruitment of the first paramedical lecturer-researchers in France³. A few years earlier, general practice had followed a similar trajectory. Key milestones include establishing a dedicated postgraduate training programme in 2004, the

appointment of the first university-affiliated academic staff in 2009, and the creation of CNU sub-section 53-03 in 2015⁴.

Another component of primary healthcare has now begun its integration into the university system: patients. Initially, involved as peers, experts or partners; patients primarily contributed by sharing their experiences of illness and healthcare. Today, patients are becoming a fully-fledged discipline in their own right. Examples include the Centre for Innovation in Partnership with Patients and the Public (CI3P) in Nice, or the Chair in Patient Research and Education at Sorbonne Nord⁵.

These new academic disciplines – general practitioners, nurses, physiotherapists and midwives – have joined other academic disciplines in primary healthcare such as dentistry and pharmacy, and several medical faculties have become health faculties³.

Research into primary care is constantly evolving, as illustrated by, for example, the dedicated RESP-IR call for proposals: a grant for inter-regional primary care research projects, or the MUST network, the multidisciplinary university network for primary care research in the territories^{6,7}. National and international publications in these disciplines are on the rise both globally and in France⁴.

The organisation of primary healthcare has shifted towards a multi-professional approach and improved coordination since the 2000s, both globally and in France. The initial fragmentation of care had revealed important limitations in terms of healthcare expenditure and quality of care, particularly for chronic conditions⁸. The declining number of doctors has also been a driving force behind this shift. This approach is reflected in France by the 2004 on the 'Coordinated Care Pathway' law centred on the general practitioner, with the aim of rationalisation, and in the 2009 HPST (Hospitals, Pa-

tients, Health, Territories) Act^{9,10}. The creation of multi-professional health centres (MSPs) and the first delegations of tasks followed the same line of thinking¹¹. Primary healthcare professionals were brought together within Regional Professional Healthcare Communities (CPTS) are multidisciplinary networks that bring together primary care professionals to improve care coordination, access to care and the organisation of care pathways, as well as developing public health prevention initiatives¹². The 'Ma santé 2022' plan, published in 2018, aimed to accelerate this transformation with a target of 1,000 additional MSPs, with the management of patients with chronic conditions, and the prescription of certain medicines by advanced practitioners¹³. In 2022 in 69% of French general practitioners were practising in group practices, compared with 70% practising alone in 2000. Of these, 40% were practising in MSPs¹⁴. The first academic accreditation of MSPs was in 2017, with 39 such MSPUs identified amongst the 2,200 existing MSPs in 2022¹⁵. The 2023 French RIST law aimed to improve access to healthcare by expanding direct access to advanced practice nurses, physiotherapists and speech and language therapists within the framework of coordinated care. It also expanded the scope of practice for chiropractors and pharmacists¹³.

The academisation and transformation of the organisation of primary healthcare are underpinned by concepts such as social responsibility. The social responsibility of a medical or health faculty lies in its '*obligation to gear its teaching, research and service activities towards the priority health needs of the population it serves*'¹⁶. In 2011, the global consensus on the social responsibility of medical schools called on universities to anticipate the health needs of populations and to forge partnerships with the health system and other stakeholders¹⁷. This social responsibility of health faculties aligns with the concept of population-based responsibility, which involves maintaining and improving the health and well-being of the population within a given territory. Relevant, coordinated health and social services that respond optimally to the expressed and unexpressed needs of the population must be accessible, not only to provide support for individuals, but also to address health determinants at an early stage¹⁸.

Despite this trend, the academisation and organisation of primary healthcare have en-

countered, and continue to encounter, resistance both at a structural level (corporatism, lack of training and leadership) and at an individual level (lack of time against a backdrop of medical staff shortages, opportunism and individualism)¹⁹. Care does not align with *Value-Based Healthcare*, a model in which primary, secondary and tertiary healthcare providers (outpatient doctors, hospitals, paramedical staff, etc.) are remunerated according to patients' health outcomes²⁰. Care is not fully integrated in line with the concept of *Clinical Population Medicine*, which involves the 'conscientious, explicit and judicious application of population health approaches to the care of individual patients and the design of health systems'. The threefold aim of this integration is to improve the patient experience, reduce costs and improve population health by combining clinical and public health perspectives²¹.

Against this backdrop, *Exercer*, the French-language general practice journal, has worked to establish a sister journal: FAJPC (*French Academic Journal of Primary Care*). FAJPC responds to the trend towards academisation with an editorial board comprised of all academic disciplines within primary healthcare (midwifery, general practice, dentistry, pharmacy, patient partners, nursing, and rehabilitation sciences). It responds to the way these disciplines are organised in the field, supporting research. It also responds to their global development, as advocated by the World Health Organisation. FAJPC is a new platform for all those involved in primary healthcare. It aims to promote French research internationally and to disseminate international research in France, ultimately improving public health. FAJPC aims to contribute to the creation of genuine primary care teams that integrate patients within a partnership framework, and to support their initial and continuing training. FAJPC aims to transform the alignment between academic development and the organisation of primary healthcare into a shared vision of health. The golden age of primary care, like the scarab, would no longer be merely a dream.

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Incorporating ecological data into a general practice prescribing guide: using the Hazard Score

INTRODUCTION

As environmental degradation increasingly contributes to the global burden of disease and premature mortality, healthcare systems are being urged to incorporate ecological considerations into clinical decision-making¹⁻³. The healthcare sector has an impact on global health, such as the environmental footprint of pharmaceutical pollution. Five million deaths per year are attributed to antimicrobial resistance². The accelerated pace of climate change is attributed to human activity, notably through massive greenhouse gas emissions. The purchase and consumption of medical drugs have been described as the main cause of CO₂ emissions in the healthcare sector^{4,5}.

In 2019, the World Organisation of Family Doctors (WONCA) called on general practitioners (GPs) to raise awareness amongst their patients by encouraging sustainable health practices⁶. In 2021, the College of General Practice (CMG) in France also issued a call to GPs regarding the environmental actions they could undertake at their own level. Suggestions included informing patients to encourage healthier lifestyles, managing practices sustainably, and global health training for healthcare professionals⁷. These documents have highlighted the importance of integrating environmental considerations into patient care. They have emphasized the role of GPs in this process as prescribers. A study has shown that general practice trainees would be willing to modify their prescribing practices if provided with accessible information on the environmental impact of drugs⁸.

In France, expenditure on healthcare services and medical supplies (CSBM) reached 235.8 billion euros in 2022, accounting for 8.9% of gross domestic product (GDP), corresponding to 3,475 euros per capita. Drugs accounted for 32,768 million euros, or 13.9% of CSBM.

Several tools have been developed to assess the environmental impact of drugs, although none had undergone validation as of 2025. The

Hazard Score (HS) is one such tool to evaluate the environmental risk associated with persistent pharmaceutical residues¹⁰. A digital tool has been developed that synthesises current evidence on the environmental impact of different treatments¹⁰.

The French National College of General Practitioner Educators publishes the Guide to Therapeutics in General Practice (TMG), a reference resource for students and general practitioners¹¹. Incorporating environmental impact data into this publication could increase awareness amongst students, general practitioners and, more broadly, those involved in primary healthcare. The editorial approach, grounded in evidence-based medicine (including grading the level of evidence) and shared decision-making, is an opportunity to incorporate environmental considerations into prescribing decisions.

The main objective of this study was to incorporate environmental risk data into the TMG by assigning Hazard Scores to the listed drugs. The secondary objective was to assess the environmental impact of drugs from the TMG that are frequently prescribed but for which no Hazard Score was available.

METHOD

Selection of drugs for analysis

The inclusion criterion was drugs listed in the fifth edition of TMG. The exclusion criteria were drugs prescribed exclusively for hospital use or for use by other specialists; drugs to be avoided (negative benefit-risk balance) according to the TMG; drugs for which the marketing authorization (MA) had been withdrawn; and drugs unavailable in France.

Data Collection

This score was developed by Janus Info and can be accessed at janusinfo.se¹². This website, which is partially available in English, is the non-commercial platform of the Pharmaceutical Committee and the Stockholm County

Criterion	Description	Score
Persistence (P)	Is degrading slowly or is potentially persistent	3
	Is degraded	0
Bioaccumulation (B)	Has a high potential for bioaccumulation	3
	Low bioaccumulation potential	0
Toxicity (T)	Very high toxicity	3
	High toxicity	2
	Moderate toxicity	1
	Low toxicity	0

Table 1. Hazard score

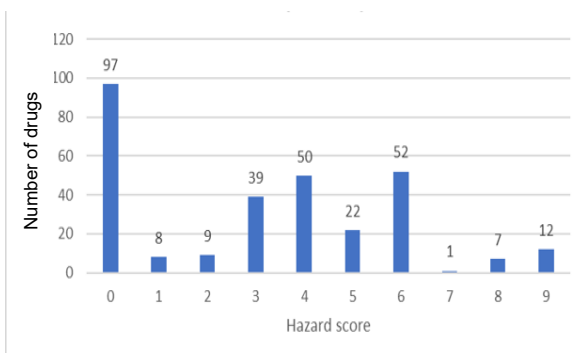


Figure 2 - Distribution of drugs according to their Hazard Score (n = 297)

Council's Health Administration. The HS assesses the environmental harm characteristics specific to each therapeutic substance. It comprises three main criteria: persistence in the environment (P), bioaccumulation in fatty tissue (B), and toxicity to aquatic organisms (T). Environmental data are sourced from pharmaceutical companies and the European Public Assessment Reports of the European Medicines Agency (EMA).

The scores for Persistence, Bioaccumulation and Toxicity (PBT) are assessed using tests

validated by the Organisation for Economic Co-operation and Development (OECD) and recommended by the EMA. The sum of these three components constitutes the HS, with values ranging from 0 to 9. The higher the HS, the more harmful the substance is to the environment.

For drugs lacking sufficient data to calculate a HS in Janus Info, we selected the 10 most frequently prescribed drugs in France in 2023 using the national health insurance 'Open Medic' data base¹³. Both scientific and grey literature were searched to help determine an environmental impact score for these 10 drugs. As the methodology differed from that of the HS, we chose to develop a separate score ranging from 0* (low environmental impact) to 9* (high environmental impact). Drugs with different trade names were grouped by their international non-proprietary name using Excel®.

Information was sourced from the drug's safety data sheet. If data were unavailable, a search was conducted on PubMed using the search query: "[international non-proprietary name] + pollutant". The inclusion criteria were studies containing data on bioaccumulation and/or environmental persistence and/or toxicity to living organisms. The exclusion criteria were studies lacking data on bioaccumulation,

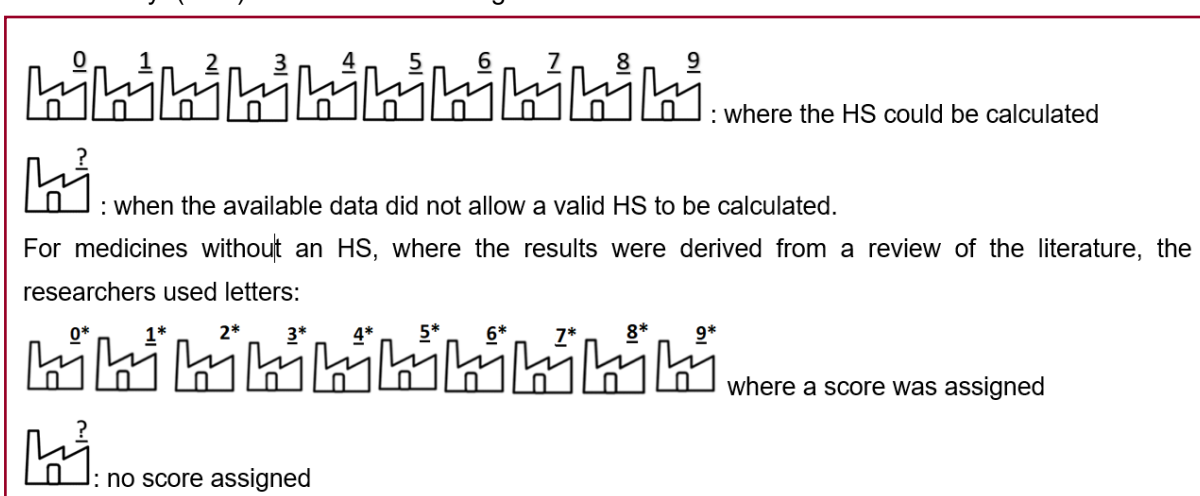


Figure 1. The Hasard score logos

environmental persistence or toxicity to living organisms, and articles that were unavailable.

The studies were selected independently by two researchers (JM and AO) based first on their titles and then on their abstracts. The articles were read in chronological order, from the most recent to the oldest, in search of PBT information on 29 November 2024. As soon as an article contained information on any of the PBT criteria, the search was halted. In the event of disagreement, the opinion of a third reviewer (QR) was sought. If any doubt remained, the article was read in full to minimize selection bias. The data were extracted into a spreadsheet. The analysis was carried out by both researchers individually and then compared. The assessment criteria were environmental PBT, rated as low, medium or high. Where data were insufficient, no rating was as-

signed.

Assignment of the Ecological Impact Marker

To reflect the ecological impact, each drug was described using its HS and represented by a logo in the TMG. The different logos are described in Figure 1.

RESULTS

Six hundred and eighty-seven medical drugs were extracted from the TMG. Twenty-three drugs were excluded: one drug whose marketing authorization had been withdrawn, nine drugs whose indication was not included in the TMG, one drug restricted to hospital use, one drug not available in France, ten drugs not prescribable by a general practitioner accor-

Medicines	HS data available on Janusinfo	Rating assigned by JM	Rating assigned by AO	Final score
Codeine	B0	P=3*, B=0*, T=3* Overall rating: 6*	P=3*, B=0*, T=3* Overall rating: 6*	
Phloroglucinol	No data	P=0*, B=0*, T=3* Overall rating: 3*	P=0*, B=0*, T=3* Overall rating: 3*	
Prednisolone	B0	P=3*, B=0*, T=3* Overall rating: 6*	P=3*, B=0*, T=3* Overall rating: 6*	
Alprazolam	No data	P=3*, B=3*, T=2* Overall rating: 8*	P=3*, B=3*, T=2* Overall rating: 8*	
Oxazepam	No data	P=3*, B=3*, T=2* Overall rating: 8*	P=3*, B=3*, T=2* Overall rating: 8*	
Amoxicillin and clavulanic acid	Amoxicillin: P3B0T3 Clavulanic acid: B0	P=3*, B=0*, T=3* Overall rating: 6*	P=3*, B=0*, T=3* Overall rating: 6*	
Tramadol	No data	P=3*, B=3*, T=2* Overall rating: 8*	P=3*, B=3*, T=2* Overall rating: 8*	
Zopiclone	B0	B=0 No overall rating	B=0 No overall rating	
Methadone	No data	P=3*, B=0*, T=3* Overall rating: 6*	P=3*, B=0*, T=3* Overall rating: 6*	
Néfopam	No data	No overall rating	No overall rating	

Table 2 - Ecological risk scores for the ten most commonly prescribed medicines in 2023

ding to the TMG, and one drug for which new prescriptions are no longer authorized. Of the 664 drugs included, the HS was available for 297 drugs (44.7%) (Appendix 1). The mean HS was 3.15 ± 2.7 . For one third of the drugs ($n = 97$, 33%), the HS was 0. The HS results are summarized in Figure 2.

Eighty-one drugs (22.1 per cent) had partial data for the HS components. No data were available to calculate the HS for 286 drugs (77.9 per cent) (Appendix 2).

Among the drugs without an HS score, the 10 most frequently prescribed drugs in France in 2023 were codeine, phloroglucinol, prednisolone, alprazolam, oxazepam, amoxicillin and clavulanic acid, tramadol, zopiclone, methadone and nefopam. Details of the scores are available in Table 2.

DISCUSSION

Main results

An HS score could be assigned to less than

half of the drugs recommended in the TMG, with an average HS of 3.15.

Comparison with the literature

In 2012, Stockholm County Council published a classification of drugs according to their environmental impact using the PBT index²⁸. The PBT index is an older, simplified version of the HS. The PBT index is a specific score or classification that assesses only three properties: persistence in the environment, bioaccumulation in living organisms and toxicity. The PBT is therefore a subset of the Hazard Score, based on criteria set by international regulations such as REACH (Registration, Evaluation, Authorization and Restriction of Chemicals). The Hazard Score is an overall, aggregated score that summarizes all the hazardous properties of a substance, whether relating to human health, the environment, etc. It includes more criteria than PBT (mutagenicity, carcinogenicity, acute toxicity, endocrine disruption, etc.). The HS generally aggregates scores for

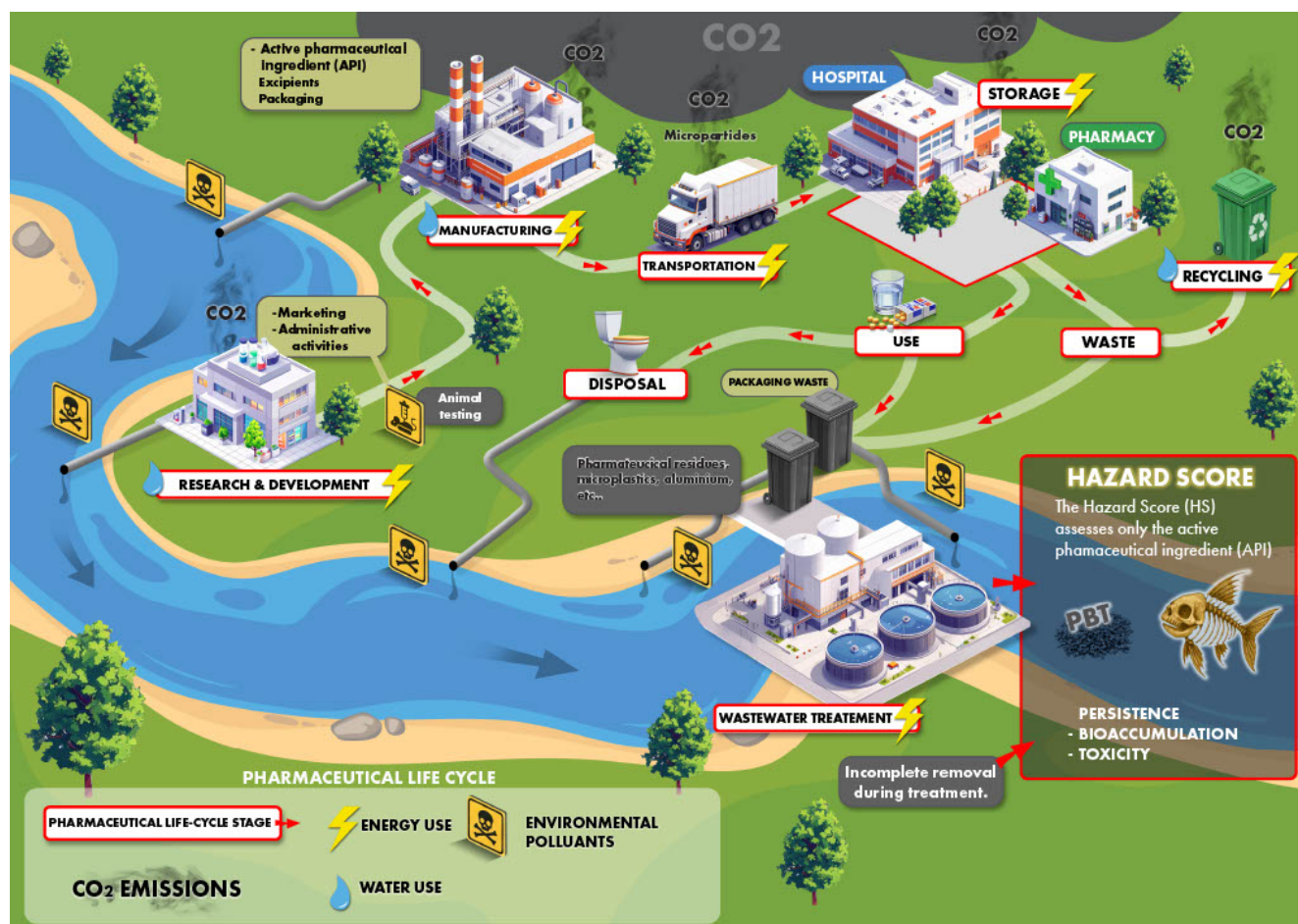


Figure 3 - Environmental impact of the drug

Drugs	Side effects
Esomeprazole	1
Lansoprazole	4
Omeprazole	4
Pantoprazole	4
Rabeprazole	5

Table 4 - HS and proton pump inhibitors

different types of hazards. (Figure 3).

Several differences were noted between the Stockholm County Council's PBT index and this study. For codeine, the scores for persistence and bioaccumulation were equivalent.

Toxicity was rated as moderate in the PBT index, whereas it was rated as very high in this study. Oxazepam had a low potential for bioaccumulation, whereas this study assessed it as high; there were no data on toxicity and persis-

tence in the PBT index. This study only identified information on bioaccumulation for zopiclone, which was assessed as low, whereas the PBT index assessed it as very high, similarly for persistence and toxicity. The PBT index contained no information on prednisolone, alprazolam, amoxicillin and clavulanic acid, tramadol or methadone. Phloroglucinol and nefopam were not included in the PBT index. There were also differences between the PBT index and the HS.

For example, chlorhexidine had an HS score of 6 (P3B0T3) whilst the PBT score was 9 (P3B3T3). Loperamide had no data in the HS, whilst it had a PBT score of 8 (P3B3T2). Omeprazole had an HS score of 4 (P3B0T1), but a PBT index of 1 (P0B0T1). Score differences may be explained by the absence of formal validation, subjective assessment methods, and the use of a 2012 PBT index, whereas the HS and the scores in this study were more recent.

Therapeutic class	International Nonproprietary Name	Form	Dosage	Hazard Score / Score for this study
Peripheral analgesics	Paracetamol 500	Tablet (tp), effervescent tablet, sachet	2 tablets per day, taken in 3 to 4 doses	
Non-steroidal anti-inflammatory drugs	Mefenamic acid	Capsule	1.5 g per day, taken in 3 doses	
	Alminoprofen	Tablet	300 to 900 mg/day in 1 to 3 doses	
	Diclofenac	Tablets	200 mg/day in 2 doses	
	Ibuprofen	Tablets	1.2 g/day in 3 doses	
	Flurbiprofen	Tablets	100 to 300 mg/day in 1 to 3 doses	
	Naproxen	Tablets	1 g/day in 2 doses	
Antispasmodics	Phloroglucinol	Tablets, oral lyophilisate, suppository	480 mg/day in 3 doses	
Progestogens	Dydrogestérone	Tablet	2 tablets daily from the 16th to the 25th day of the cycle	

Table 3 - Treatments for primary dysmenorrhoea according to the TMG, including the ecological risk score¹¹

The EMA considers vitamins, electrolytes, amino acids, peptides, proteins, carbohydrates, lipid proteins, vaccines and medicinal herbs to pose no environmental risk²⁹. Ninety-three drugs from the TMG were affected; their HS was 0.

In May 2023, the French government issued a roadmap for the ecological planning of the healthcare system. It highlighted the major role played by the healthcare system in relation to biodiversity, the depletion of natural resources, access to fresh water, and the degradation and pollution of natural environments³⁰. This roadmap is intended as an initial resource for general practitioners in France, facilitating their access to available environmental data on drugs.

In February 2025, the National Health Insurance Fund announced the creation of a company called Ecovamed to assess carbon footprint, demonstrating the relevance of taking environmental impact into account³¹. Ecovamed offers a solution for life cycle assessment and the evaluation of the carbon footprint of drugs, medical devices, care pathways, active pharmaceutical ingredients and cosmetics, and, more generally, of chemical, biotechnology and polymer products. It helps manufacturers better understand the environmental impact of their products and to find solutions to reduce these impacts.

The French Society of Anesthesia and Intensive Care has put forward recommendations on the use of anaesthetic vapors and gases, intravenous drugs, medical devices and the working environment to reduce the environmental impact of general anesthesia; however, these do not apply to general practice³².

Strengths and weaknesses

This study marked the first time environmental data had been incorporated into an evidence-based prescribing guide for general practice in France. These data will be included in the sixth edition of the TMG. An example of the practical use of this tool is shown in Table 3.

All drugs recommended in general practice have been included. No tool has yet been validated internationally, and differences exist between the scores. The HS could not be determined for 55.3% of the treatments recommended in the TMG. In this study, we calculated a separate score for 10 frequently prescribed drugs for which no HS was available. The decision to limit the analysis to the 10 most dispensed drugs was arbitrary. The number of packs sold is an imperfect measure, as the number of drugs in each pack varies. The method chosen for these 10 drugs was based on the HS criteria, using a pragmatic approach due to limited available resources. A single database and a single article meeting one of the criteria missing from the HS was deemed sufficient; and the analysis by

the researchers was subjective. To minimize bias, the analysis was carried out independently by both researchers. As the methodology was deemed weaker than that of HS, the authors limited their research to 10 drugs. These results will not be included in the next TMG edition.

This study focused on the direct impact of active substances on the natural environment. An HS score of 0 does not imply the absence of environmental impact. Further research is needed to evaluate the environmental impact of production methods, packaging, transport, excipients and the recycling of unused drugs^{33,34}.

CONCLUSION

Despite the lack of a single or validated reference framework to date, the environmental impact of a significant proportion of the treatments used in primary care could be assessed. Their inclusion in the sixth edition of the TMG will be a first step towards more responsible and sustainable prescribing practices.

Where the clinical benefit-risk profile is equivalent, a drug's environmental impact now appears to be a relevant criterion for choice, in line with the principles of environmental-based medicine. For example, in the case of proton pump inhibitors, in the absence of comparative data on efficacy and safety, GPs may favor esomeprazole due to its lower environmental impact (Table 4). Given the current global health challenges, it is no longer simply a matter of raising awareness but implementing concrete changes in the tools, practices and training of general practice.

The authors have declared no conflicts of interest regarding the data published in this article. The financial interests of each of the article's authors are available online at www.transparence.gouv.fr.

Abstract

Introduction. In 2021, the French College of General Practice called on general practitioners to incorporate environmental considerations into their clinical practice.

Objective. To incorporate environmental risk data for drugs listed in the 5th edition of the 'Guide to Therapeutics in General Medicine' published by the National College of General Practitioners, using the Hazard Score.

Method. The environmental impact of the selected drugs was assessed using a Hazard Score ranging from 0 to 9, available through Janusinfo.se. Developed independently of pharmaceutical manufacturers this Swedish score incorporates three dimensions: environmental persistence, bioaccumulation in fatty tissues and toxicity to aquatic organisms. For drugs without an available Hazard Score, the ten most frequently prescribed drugs in France in 2023 were identified. A literature review was carried out to assign a rating ranging from A (low environmental impact) to C (high impact).

Results. Six hundred and sixty-four drugs were included. A Hazard Score was assigned to 297 drugs (44.7%). The average Hazard Score was 3.15. Ninety-seven drugs (32.7%) had a Hazard Score of 0. Among the 367 drugs without a Hazard Score (55.3%), phloroglucinol was graded B. Codeine, prednisolone, alprazolam, oxazepam, amoxicillin and clavulanic acid, tramadol, and methadone were graded C. No grade was given to zopiclone and nefopam.

Conclusion. This evaluation provides general practitioners with ecological risk data, facilitating environmentally conscious prescribing practices. Integrating such information into prescribing resources represents a crucial step towards sustainable medical practice.

Keywords: General Practitioners–Drugs–Environmental Pollution

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Pre-disclosure of cancer in general practice: A key stage in patient management

INTRODUCTION

The disclosure of a cancer diagnosis is a key stage in the care pathway for patients with cancer^{1,2}. The experience of this disclosure is often difficult for patients^{3,4}. The disclosure of a cancer diagnosis has been formalised in France since the development of the first Cancer Plan (2003–2007): the Disclosure Framework (DA)⁵. This institutional framework provides a structure for the communication of a cancer diagnosis so that patients can receive information, be listened to and receive support under the best possible conditions. Since January 2006, this DA has been rolled out across all cancer centres in France. However, coordination between hospital teams and local GPs needs to be strengthened^{5,6}.

The diagnosis of cancer is not delivered by a single doctor on a single occasion, as the 'medical timeframe' of the DA – long associated solely with the 'diagnosis consultation' – might suggest. It is a fragmented process, spread out over time and across different healthcare professionals, which must take into account the patient's knowledge and understanding^{7,8}. The first mention of the disease may take place in a general practice setting, prior to the specialist consultation, by non-oncologists and particularly GPs^{3,9}. This calls into question the role of the GP in the specialist consultation and their involvement in preparing the patient for the cancer diagnosis. GPs, as primary care physicians, are involved in the prevention, screening and sometimes diagnosis of cancers¹⁰. They can be regarded as 'catalysts' for the cancer disclosure, as they are on the front line when the disease is suspected. The disclosure consultation with the specialist is rarely the starting point, but rather the culmination of a multi-professional care pathway initiated in the community, prior to the diagnosis, and for which the GP is often the coordinator.

GPs have identified three phases in their practice: the pre-disclosure phase¹¹, the disclosure phase, and the post-disclosure phase of cancer¹¹. We have therefore defined the pre-disclosure as the moment when the GP, during the patient's diagnostic journey, first raises the possibility of cancer with the aim of preparing the patient for this eventuality, without necessarily having a formal diagnosis. This pre-disclosure is a vague stage for which there is currently no established framework. Few studies have focused solely on this phase of the disclosure process¹¹. Beyond practical experience in the field, knowledge is limited regarding how GPs organise the pre-disclosure, how it unfolds, and the difficulties encountered.

The main objective of this study was to examine the process and content of cancer screening carried out by GPs. The secondary objectives were to examine the approaches

to screening already adopted by GPs; and to identify the difficulties encountered and the reasons why screening was not carried out.

MATERIALS AND METHODS

This retrospective, observational study assessed the professional practices of general practitioners who had a registered patient referred for a diagnosis disclosure consultation at the IUCT-O (Toulouse University Cancer Institute – Oncopôle). A quantitative method was chosen to assess the frequency with which the pre-disclosure was carried out and the frequency of the topics explored.

The questionnaire

A literature review was conducted using the PubMed, EM Premium and Google Scholar databases, as well as French repositories (the Haute Autorité de Santé and the Institut National du Cancer). The keywords used for this search were: general practitioner, pre-disclosure, disclosure, diagnosis, cancer. The questionnaire was developed based on data from the literature^{5,7,9,11}, which was drawn primarily from articles on cancer disclosure.

The questionnaire was divided into six sections: [1] the epidemiological characteristics of the doctors; [2] whether the health assessment had been carried out; [3] the conduct of the health assessment; [4] its content; [5] the difficulties encountered; and [6] the tools to be developed to assist GPs during this consultation. It comprised 32 closed-ended questions and one open-ended question (Appendix 1). Doctors who had not carried out a pre-disclosure were not asked about sections [3], [4] and [5] of the questionnaire and answered 16 questions. Doctors who had carried out the pre-disclosure were not asked about the end of section [2] and were required to answer 30 questions. The questionnaire was anonymised. It was tested with six GPs to assess its feasibility, relevance and completion time. Following revisions, it was made available online via the Google Forms® application.

Selection of patient records

ICD-10 (International Classification of Diseases) coding was applied to data from the medical information department of the Toulouse University Cancer Institute (France). This enabled the selection of records for patients who had been diagnosed with cancer between 1 October and 31 December 2017. The characteristics of the patients were recorded.

The inclusion criteria for patient records (PRs) were:

- Adult patients with solid or haematological cancer,
- Cancer-related admissions occurring between 1 October and 31 December 2017.

The exclusion criteria were:

- Patients who had previously undergone cancer surgery,
- Patients who, upon retrospective review, were found not to have cancer,- Patients unable to give free and informed consent (minors, patients with mental or cognitive disorders, and patients who had died at the time of case selection),- Patients whose medical records were incomplete,
- Patients who were their own GP or whose GP was a family member,
- Patients whose GP had already been included in the study.

Following this stage, the administrative data from the selected patient records enabled us to contact them by telephone to obtain their verbal consent to their inclusion and to the request that would be made to their GP.

Following this telephone contact, the following patients were excluded:

- those refusing to take part in the study,
- those who could not be reached by telephone after three unsuccessful calls,
- treatment abroad.

Recruitment of GPs

The questionnaire was sent to GPs whose patients had agreed to take part in the study.

Initially, the questionnaire was sent to the patient's registered GP via secure email. If no reply was received within seven days, a telephone call was made. Following this call, and provided the GP had given their consent, the questionnaire was returned via the method chosen by the doctor: secure email, fax or post. If there was no response, the email was sent twice before a final telephone call was made. GPs who had not responded within one month of the last reminder were considered non-responders.

In total, GPs were excluded if they:

- had refused to take part in the study,
- could not be contacted,
- remained non-responders after follow-up attempts.

Data analysis

Data collection took place between 1 December 2017 and 31 March 2018, via post and fax. The data were then analysed using *Microsoft Excelmac2011*® and the INSERM *BiostaTGV*® website. Socio-demographic characteristics and variables of interest were described in terms of numbers and percentages for quantitative variables. In order to compare the qualitative variables according to anticipation of the pre-disclosure, the duration of the pre-disclosure and the use of the word 'cancer', a chi-squared test was carried out, or Fisher's exact test where the former was not applicable (theoretical sample sizes of less than 5). The alpha significance level used for these tests was 0.05.

Regulatory aspects

This study was conducted outside the scope of the Jardé Act. The Ethics Committee of the University Department of General Practice in Toulouse issued a favourable opinion regarding the conduct of this study on 12 August 2017, No. 2017-014 (Appendix 2). A compliance application was submitted to the CNIL via Reference Method No. 3, requesting oral consent from patients and GPs for their participation in

the study: No. 2081263 v 0 (Appendix 2).

RESULTS

Between 1 October and 31 December 2017, 555 cases of cancer were recorded, and we received 81 responses from GPs (Figure 1), 82.7% of whom had seen their patients in consultation prior to the diagnosis being confirmed. Of the 81 patients included, 61.7% ($n = 50$) were women. The mean age was 56.3 years, with a median of 58 years. The three most common cancers among women were breast cancer, haematological cancers and thyroid cancer. For men, the most common were ENT cancers, haematological cancers and testicular cancer. The GP characteristics are detailed in Appendix 3. The 81 GPs had been in practice for an average of 21 years (SD: 11.3 years) and had been treating their patients for more than 10 years in 44.4% of cases. 74.1% ($n = 60$) of them practised in a group practice or a multi-professional health centre.

Planning for the Pa

A cancer screening test was carried out in two-thirds of cases and had been anticipated by 75.9% of GPs ($n = 41/54$) (Table 1). Of the doctors preparing for this consultation, 68.0% had considered how to broach the possibility of cancer. When GPs specifically researched the treatment and prognosis of the disease, consultations were significantly longer, lasting more than 30 minutes ($p < 0.01$ and $p = 0.03$) (Table 2). GPs who had planned for palliative care were more likely to discuss supportive care and the adverse effects of treatments with their patients ($p = 0.07$ and $p = 0.08$). Having a histological diagnosis did not appear to influence the anticipation of the pre-disclosure (46.3% versus 30.8%, $p = 0.32$) (Table 2).

The palliative care consultation lasted more than 15 minutes in 88.9% ($n = 48$) of cases and more than 30 minutes in 25.9% ($n = 14$) of cases (Table 1). The duration of the consultation was not influenced by the type of topics discussed, nor by the decision to withhold certain information during the consultation. During these consultations, 81.5% of doctors sought to find out what their patients already knew about their health condition and 87.0% asked what they wanted to know. The two most frequently discussed topics were cancer treatment and supportive care (Table 2).

The content of the Pa

The word 'cancer' was mentioned in 70.4% of the pre-disclosure consultation. It was mentioned by more than three-quarters of GPs who had planned the pre-disclosure consultation and by half of those who had not (Table 2). Having the histological diagnosis did not influence the perception that the doctor was withholding information.

Over 80% of GPs were in favour of limiting information to give the patient hope, to conduct the pre-disclosure in several stages, and to avoid overwhelming the patient with information (Figure 2). GPs suggested a follow-up consultation after this pre-disclosure in 68.5% of cases. This approach to care made it possible to plan the pre-disclosure in advance ($p = 0.01$), to increase the consultation time to over 30 minutes ($p = 0.01$) and to use the word 'cancer' more frequently ($p = 0.03$) (Table 2).

CONDUCT OF THE PRE-DISCLOSURE		
	N = 54	(%)
Early pre-disclosure:	41	(75.9)
Duration of consultation (min):		
< 15	6	(11.1)
15 to 30	34	(63.0)
> 30	14	(25.9)
Patient accompanied by a family member	20	(37.0)
Preliminary notification given:		
After the discovery of a suspicious clinical sign	31	(57.4)
Following an abnormal screening test	15	(27.8)
Following an abnormal follow-up test	42	(77.8)
After the biopsy was performed	25	(46.3)
After receiving the pathology report	23	(42.6)
At the request of a colleague	2	(3.7)

Table 1 - Description of the pre-disclosure

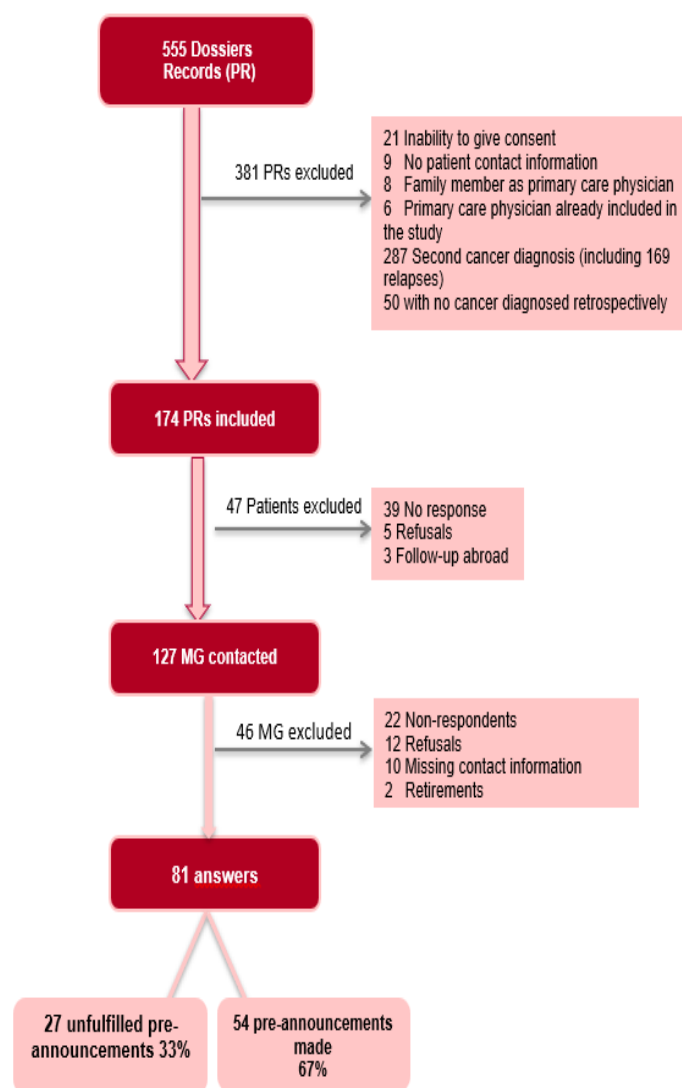


Table 1 - Flowchart

Challenges and benefits of pre-disclosure

The pre-disclosure did not present any difficulties for 20.4% (n = 11) of GPs. For the others, the difficulties were due to a lack of prognostic information (66.7%), therapeutic information (64.8%), diagnostic uncertainty (27.8%) and emotional distress. GPs most often sought information by consulting specialist colleagues (75.3%) or by referring to online resources (70.4%). Seventy-nine percent of doctors would like to have access to additional oncological information resources, and 56.8% were interested in training on palliative care.

For 98.1% of GPs, the pre-disclosure had been helpful in their patient's acceptance of the illness, and 94.5% felt it had played an important role in the overall process of informing their patient of their cancer. 82.7% (n = 67) of GPs were in favour of systematically incorporating a pre-disclosure into the cancer diagnosis process. One third of GPs (n = 27/81) did not carry out the pre-disclosure, although 48.1% (n = 13/27) would have liked to. The most common reason for not carrying it out (51.8%, n = 14) was related to feasibility, as the patient had not been seen in a GP consultation prior to diagnosis. 29.6% of GPs (n = 8) had not discussed the suspected cancer diagnosis because pathological results were not yet available at the time of the consultation (Figure 3). None of the GP characteristics or the type of cancer contributed to the conduct of the pre-disclosure consultation.

DISCUSSION

Two-thirds of GPs had raised the possibility of cancer with the patient prior to the Disclosure Procedure (DP). Three-quarters of GPs had prepared for this consultation. GPs who prepared for the pre-disclosure by seeking information on the treatment and prognosis of the disease had significantly longer consultations ($p < 0.05$). Planning to see the patient again was associated with a comprehensive pre-disclosure consultation: one that was lengthy, scheduled in advance, and during which the word 'cancer' had been mentioned. The more GPs felt involved in their patient's cancer diagnosis, the more they invested in the pre-disclosure process ($p < 0.01$).

Strengths and limitations

The main strength of this study lies in its originality. To

	Anticipation of the Preliminary Announcement (Pa) (N = 54):						
	Anticipation (N = 41)		No Anticipation (N = 13)		Total (N = 54)		p
	N	(%)	N	(%)	N	(%)	
Topics covered during the practical session:							
Treatments	35	(85.4)	9	(69.2)	44	(81.5)	0.23 ^F
Stage of cancer	12	(29.3)	2	(15.4)	14	(25.9)	0.47 ^F
Prediction	17	(41.5)	4	(30.8)	21	(38.9)	0.49 ^C
Supportive care	21	(51.2)	3	(23.1)	24	(44.4)	0.07 ^C
Adverse effects of treatments	15	(36.6)	1	(7.7)	16	(26.6)	0.08 ^F
Consultation duration < 30 mins	28	(68.3)	12	(92.3)	40	(74.1)	0.14 ^F
Final diagnosis following histopathological findings	19	(46.3)	4	(30.8)	23	(42.6)	0.32 ^C
Performed following abnormal follow-up examination	34	(82.9)	8	(61.5)	42	(77.8)	0.10 ^C
Pronunciation of the word 'cancer'	31	(76.6)	7	(53.9)	38	(70.4)	0.17 ^F
Knowing what the patient already knew	32	(78)	12	(92.3)	44	(81.5)	0.42 ^F
Knowing what the patient wanted to know	35	(85.4)	12	(92.3)	47	(87.0)	1.00 ^F
Information provided to the patient	2	(4.9)	0	(0)	2	(3.7)	0.23 ^F
Believe they have answered the patient's questions	21	(51.2)	6	(46.1)	27	(50.0)	0.75 ^C
Appointment booked remotely	30	(73.2)	5	(38.5)	35	(64.8)	0.04^F
	Duration of Pa (if Pa was anticipated):						
	< 30 mins, (N = 28)		> 30 mins, (N = 13)		(N = 41)		p
Before the consultation, did you:							
- Thought about how to approach the diagnosis	18	(64.3)	10	(76.9)	28	(68.3)	0.49 ^F
-Has researched treatments	4	(14.3)	9	(69.2)	13	(31.7)	<0.01^F
-Has carried out research into prognosis	5	(17.8)	7	(53.8)	12	(29.3)	0.03^F
-Sought specialist advice	6	(21.4)	3	(23.1)	9	(22.0)	1.00 ^F
	Pronunciation of the word 'Cancer':						
	Pronounced (N=38)		Not pronounced (N = 16)		Total (n=54)		p
Completed after:							
an abnormal clinical sign	24	(63.2)	7	(43.8)	31	(57.4)	0.18 ^C
An abnormal screening result	12	(31.6)	3	(18.8)	15	(27.8)	0.50 ^F
An abnormal follow-up examination	30	(78.9)	12	(75)	42	(77.8)	0.70 ^F
Performing a biopsy	21	(55.3)	4	(25)	25	(46.3)	0.07 ^F
Pathology	18	(47.3)	5	(31.3)	23	(42.6)	0.27 ^C
A request from a colleague	2	(5.3)	0	(0)	2	(3.7)	1.00 ^F
Scheduled consultation with Pa	31	(81.6)	10	(62.5)	41	(75.9)	0.17 ^F
Remote appointments	28	(73.7)	7	(43.8)	35	(64.8)	0.03^C
Consultation duration < 30 mins	26	(65)	14	(87.5)	40	(74.1)	0.18 ^F

Table 2 - Characteristics of the pre-disclosure (Pa) according to its duration, how far in advance it was given, and whether the word 'cancer' was mentioned. ^F= Fisher's test; ^C= Chi-squared test; p<0.05 = significant result; Pa = pre-disclosure

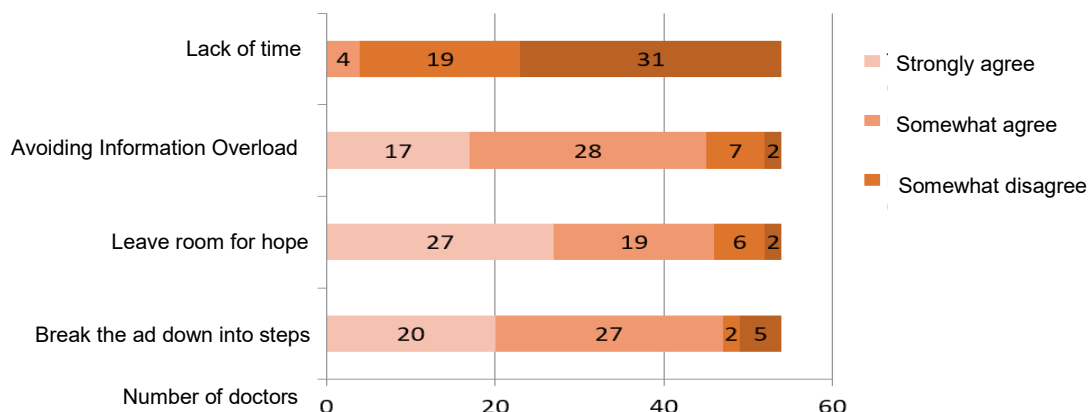


Figure 2 - General Practitioners' Views on the Reasons for Restricting Information Provided to Patients During the Pre-Disclosure Phase

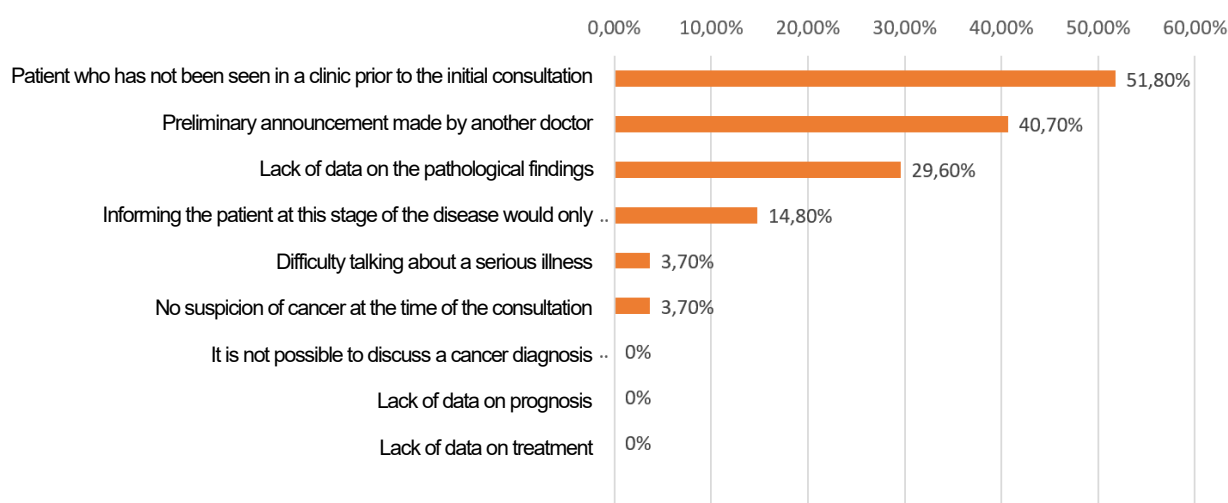


Figure 3 - Reason for general practitioners' failure to provide advance notice (n = 27)

the best of our knowledge, no other study has focused exclusively on this 'pre-disclosure phase of cancer in general practice. Our study, being descriptive in nature, provides an overview of the current situation, enabling a better understanding of GPs' practices. The 63% response rate is very satisfactory, due to the recruitment methods: a doctor contacting GPs by telephone and asking GPs about a patient from their own practice. This method enabled us to minimise recruitment bias and recall bias among GPs. The latter was also reduced by the short interval between the consultation during which the diagnosis was disclosed and patient recruitment.

We chose the IUCT-O for patient recruitment as it is one of the leading cancer centres in our region. A selection bias exists due to the single-centre nature of the study. The median age of patients at the time of diagnosis was 12 years younger than the median age in France in 2023 (70 years)¹². This difference can be explained by the different types of cancer found in our sample. Certain cancers that are relatively common in our population, such as thyroid cancer (8.6 per cent), testicular cancer (4.9 per cent) and sarcomas (4.9 per cent), are diagnosed at a young age, whereas colon and lung cancers are under-represented.

The patient's care pathway

In our study, 82.7% of GPs surveyed had seen their patient in consultation prior to the cancer diagnosis being announced. GPs contribute to the screening and diagnosis of cancers and to the coordination of the care pathway. This involvement promotes better use of available resources for patients with cancer, notably a reduction in the use of A&E departments and improved access to supportive care^{6,13,14}, and falls entirely within their remit¹⁵. In order to improve coordination, GPs must be involved in the patient's diagnostic pathway through their participation in the cancer care pathway¹⁶. This early and systematic involvement of GPs would improve patient support and the implementation of the diagnostic process. 94.5% of the GPs surveyed in our study felt they had played an important role in the overall diagnosis of cancer. GPs are involved in the diagnostic pathway for patients with cancer¹⁷. They are consulted by their patients or colleagues beforehand (pre-disclosure), afterwards (post-

disclosure), during the disclosure itself and sometimes during the multidisciplinary team (MDT) meeting^{11,18}. For patients, the diagnostic pathway can sometimes be unclear and complex¹⁹. Most patients consult their GP within a week of the diagnosis consultation¹¹ and the importance of a post-diagnosis consultation has been recognised in France since 2017. GPs have access to a wealth of medical, social and psychological information about their patients, enabling them to act as care coordinators with other specialists^{18,20}. The development of pre-disclosure could be beneficial in integrating the patient at an early stage into the diagnostic and subsequent care pathway. This would help strengthen the partnership between specialists and GPs in order to avoid unnecessary consultations or visits to A&E⁶. This approach is therefore likely to improve coordination between community and hospital settings and the quality of care²¹.

Advance notification

We can describe the pre-disclosure as a lengthy consultation, during which doctors assess the patient's fears and expectations. They may limit the information provided in order not to overwhelm the patient, to give them hope, and to conduct a phased pre-disclosure. This consultation is longer than the average for French GPs (16.4 minutes), which is already long by international standards²². This allows for taking 'the necessary time' recommended when addressing a serious illness⁷. Breaking the disclosure down into stages so as not to overestimate the patient's capacity to process the information and gradually leading them towards the diagnosis is a recognised communication approach for serious illnesses^{3,23}. It would be necessary to establish a structured method to guide the doctor in this communication, considering the patient's emotional reaction, which has already been factored into the delivery of the news. This requires active and empathetic listening to support the patient in coming to terms with the illness²³. In our study, anticipating the patient's emotional response enriches the content of the communication and enables patients to be included in a care pathway by offering them follow-up care ($p = 0.04$). This helps to build a relationship of trust and

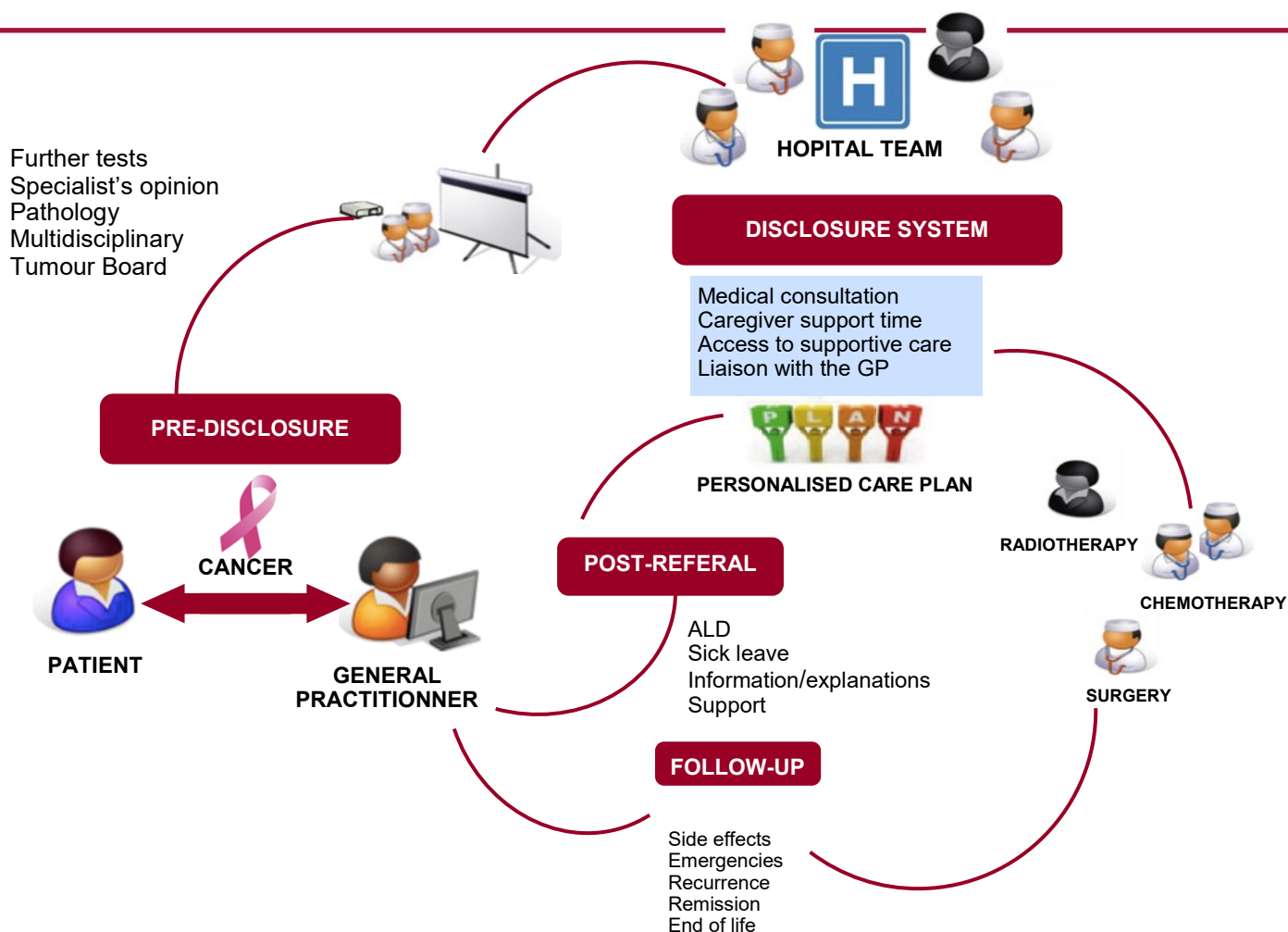


Figure 4 - The role of the preliminary diagnosis by the GP in the overall cancer diagnosis

ongoing support for the patient, guiding them through the various stages of their diagnosis.

During the initial consultation, GPs feel at a loss due to the lack of prognostic and therapeutic information regarding the disease. They feel isolated in their role as primary care providers²⁴. The GP plays a central role in the overall cancer disclosure process; their role begins prior to the disclosure, with the pre-disclosure consultation, continues after the diagnosis during the post-disclosure phase, and, of course, throughout the patient's care (Figure 4).

CONCLUSION

Our study highlights the importance of the 'pre-disclosure' of cancer, carried out by two-thirds of GPs. This is an essential but poorly structured stage of the care pathway. Three-quarters of GPs carry out the 'pre-disclosure' and approach it with preparation and commitment. They plan the content in advance and take their time, particularly when follow-up is anticipated. However, difficulties persist, notably due to a lack of information on prognosis and treatment, as well as GPs' sense of isolation in this role. The existence of a standardised pre-disclosure consultation, included in the diagnosis process, would facilitate a smoother diagnostic pathway for patients and ensure consistency in care. Structuring this consultation, with appropriate tools and enhanced support for

GPs, would foster a more calm and gradual dialogue with patients. By strengthening training and developing specific resources, it would be possible to optimise this key phase, leading to more humane and efficient care.

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Conflicts of interest: All authors have declared on the ICMJE form all their links or potential conflicts of interest (financial activities, links with companies or institutions) relating to the submitted work. They declare no conflicts of interest.

Abstract

Background. The diagnosis of cancer is communicated to a patient during a consultation designed to deliver the news, which incorporates a structured timeline and a multidisciplinary approach. However, prior to the start of oncological care, the patient will need to consult their general practitioner (GP). The GP is involved in the early stages of the diagnostic pathway, carrying out screening, identifying symptoms and coordinating the pathway. This consultation prior to the diagnosis, known as the 'pre-disclosure consultation', has been little studied. Objective: To determine the content of the 'pre-disclosure' consultation carried out by GPs in practice.

Method. A retrospective quantitative study was conducted using a questionnaire among GPs who referred patients who had a cancer disclosure consultation between 1 October and 31 December 2017 in Toulouse, France. The online questionnaire comprised 34 closed-ended questions and one open-ended question. Data analysis was descriptive.

Results. Of the 174 patient records selected, corresponding to 174 different GPs, 81 GPs responded. Fifty-four had carried out a 'pre-disclosure' consultation (89% lasting more than 15 minutes, 26% more than 30 minutes). Half mentioned supportive care; almost all considered it helpful for coming to terms with the illness, and 85 per cent limited the information in order to deliver the news in stages. Conversely, 27 of the GPs had not given a 'pre-disclosure', half of whom would have liked to have done so.

Conclusion. The 'pre-disclosure' is carried out informally. GPs take the time to organise this consultation and tailor it to the patient. However, a lack of information and the isolation of GPs complicate the 'pre-disclosure'. Integrating it into the disclosure process could improve the coordination of care. Structuring the 'pre-disclosure' using appropriate tools and providing better support for GPs is necessary to support patients.

Keywords. General Practice, Cancer, Disclosure

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APPENDIX 1 - QUESTIONNAIRE FOR GENERAL PRACTITIONERS

PATIENT IDENTIFICATION NUMBER:

GENERAL CHARACTERISTICS: EPIDEMIOLOGY

- 1-You are:
A man ☐ A woman ☐
- 2-What is your year of birth? (Years)
...
- 3-Do you practise in a:
Rural ☐ Semi-rural ☐ Urban ☐
- 4- In which year did you set up your practice?
...
- 5- Do you practise in a practice:
On your own ☐
In a group practice ☐
In a multidisciplinary health centre (MSP) ☐
- 6-Do you hold any additional qualification(s) in:
Oncology ☐ Palliative care ☐
Pain management ☐ None of the above three ☐
- If so, what type:
DU ☐ DESC ☐ Certificate ☐
- 7- How long have you been treating this patient?
0–5 years ☐ 6–10 years ☐ >10 years ☐
- 8- Do you consider that you played a part in your patient's cancer diagnosis?
Yes ☐ No ☐

PRE-DIAGNOSIS: THE SUSPICION OF CANCER:

*We define the 'pre-disclosure' of cancer as:
The moment when you discuss the possibility of cancer with your patient in order to prepare them for this eventuality prior to the 'diagnosis consultation', whether the diagnosis is hypothetical or confirmed.*

- 1- Did you discuss the possibility of cancer with your patient before they saw the specialist for the diagnosis consultation (oncologist, surgeon)?
Yes ☐ No ☐

If you tick YES, go straight to Part III of the questionnaire. Otherwise, continue.

- 2- You did not raise this possibility with this patient because:
Tick the options that you consider most relevant.
- 3- Would you have liked to prepare the patient for this news before they saw the specialist?
Yes ☐ No ☐

You may proceed directly to Part VI of the questionnaire, without completing pages III, IV and V.

PRE-DISCLOSURE: PROCEDURE / CONTEXT

- 1- Had you planned to discuss the possibility of cancer during the consultation?
Yes ☐ No ☐
- 2- How long did this consultation last?
- Less than 15 minutes or so ☐
-Between 15 and 30 minutes ☐
-More than 30 minutes or so ☐

3- Was the patient accompanied by one or more people?

Yes ☐ No ☐

If so, who:

Family ☐ Friend ☐ Healthcare staff ☐ Other(s): ...

4- Before this consultation, did you:

	YES	NO
Thought about how to deal with this diagnosis		
Researched the proposed treatments		
Researched the prognosis		
Sought a specialist's advice on management		

5-Did you give this preliminary notice:

	YES	NO
After the discovery of a suspicious clinical sign		
Following an abnormal screening test (population-based or individual)		
Following an abnormal follow-up test (imaging, laboratory tests)		
Following a biopsy		
Following receipt of the pathological report confirming the diagnosis of cancer		
At the request of a colleague		

IV. PRELIMINARY NOTIFICATION: CONTENTS

1- Have you tried to find out:

- What the patient already knew about their condition?

Yes ☐ No ☐

- What they wanted to know about their health?

Yes ☐ No ☐

2- Did you use the word 'cancer'?

Yes ☐ No ☐

3- Did you deliberately withhold certain information in order to:

	Strongly agree	So-mewhat agree	So-mewhat disagree	Strongly disagree
Make a gradual announcement in several stages				
Give the patient hope				
Avoid giving too much information all at once				
Due to a lack of time				

4- Did you say:

	YES	NO
Possible treatments (surgery, radiotherapy, chemotherapy)		
The stage of the cancer		
The prognosis		
Possible supportive care		
Side effects of treatments		

5- Have you provided your patient with any materials (written documents, diagrams, online resources, etc.) explaining their condition?

Yes ☐ No ☐

6- Do you feel you have answered all your patient's questions?

Yes ☐ No ☐

7- Did you arrange another appointment with the patient at the end of this consultation?

Yes ☐ No ☐

PRE-NOTIFICATION: FEELINGS AND USEFULNESS

1- Did you feel challenged during this consultation in relation to:

	Yes	No
Diagnostic uncertainty		
A lack of prognostic information		
A lack of therapeutic information		
Due to relational/emotional difficulties		

2-Do you think this consultation was helpful for the patient?

Yes ☐ No ☐

3-What role do you think you played in the 'overall disclosure' of your patient's cancer?

- Very important ☐
- Quite important ☐
- Not very important ☐
- Not very important ☐

AREAS FOR IMPROVEMENT AND TOOLS TO BE DEVELOPED:

1-Do you think that a preliminary cancer diagnosis by the GP, prior to the specialist's diagnosis, should be systematically incorporated into the disclosure process?

- I completely agree ☐
- Somewhat agree ☐
- Somewhat disagree ☐
- Strongly disagree ☐

2-Would you like to have access to additional information resources on cancer?

Yes ☐ No ☐

If yes: Tick the relevant options

	About the disease	About treatment	On the prognosis	On the supportive care available
For yourself				
To give to the patient				

3-What oncology information resources do you use?

- Cancer care network ☐
- Websites (HAS, Oncomip, etc.) ☐
- Guidelines/medical press ☐
- University hospital teaching ☐
- Colleagues ☐
- Continuing medical education / Peer group ☐

4-Are you familiar with the Oncomip website?

Yes ☐ No ☐

5-Would you be interested in further training on how to discuss the possibility of cancer with your patients?

Yes ☐ No ☐



APPENDIX 2 - APPROVAL BY THE ETHICS COMMITTEE OF THE DEPARTMENT OF GENERAL MEDICINE AT THE UNIVERSITY OF TOULOUSE

**Commission Ethique du Département de
Médecine Générale de Midi Pyrénées**

Secrétariat : *Dr Motoko DELAHAYE*
30 Avenue des Arcades, 12000 Le Monastère
Tél. : 05.65.42.58.69 – Tél. Port : 06.88.05.55.52 – motoko.delahaye@dumg-toulouse.fr

Président : Mme Laurencine VIEU
Secrétaire : Mme Motoko DELAHAYE

**AVIS A LA COMMISSION ÉTHIQUE DU DÉPARTEMENT UNIVERSITAIRE DE MÉDECINE
GÉNÉRALE DE MIDI-PYRENNÉES**

Renseignements concernant le demandeur :

Nom : BERGES Magali
Qualité : Médecin généraliste non thésée
Adresse : 15 rue Sainte Marthe 31000 TOULOUSE
Courriel : magalibergeres@gmail.com
Numéro de téléphone : 06 87 11 54 24

Renseignements concernant le promoteur :

Nom : Faculté de médecine de Toulouse Rangueil, DUMG, sous la direction du Dr Marie-Eve ROUGE-BUGAT
Qualité : Docteur en médecine, Maître de stage universitaire
Adresse :
Courriel : marieeve.rouge-bugat@dumg-toulouse.fr

Titre complet de la recherche :

Point de vue des médecins généralistes au sujet de la réalisation d'une pré annonce de cancer en
amont de la consultation d'annonce.

AVIS DE LA COMMISSION (Réservé à la Commission)

AVIS FAVORABLE

N° 2017-014

LE 12/8/2017

Dr Motoko Delahaye

APPENDIX 3 - CNIL DECLARATION OF COMPLIANCE USING REFERENCE METHOD NO. 3



RÉCÉPISSÉ

DECLARATION DE CONFORMITÉ A
UNE MÉTHODOLOGIE DE
RÉFÉRENCE

Numéro de déclaration

2081263 v 0

du 06 juillet 2017

Madame BERGES Magali
MÉDECIN GÉNÉRALISTE REMPLAÇANT
15 RUE SAINTE MARTHE
31000 TOULOUSE

À LIRE IMPÉRATIVEMENT

La délivrance de ce récépissé atteste que vous avez transmis à la CNIL un dossier de déclaration formellement complet. Vous pouvez désormais mettre en oeuvre votre traitement de données à caractère personnel.

La CNIL peut à tout moment vérifier, par courrier, par la voie d'un contrôle sur place ou en ligne, que ce traitement respecte l'ensemble des dispositions de la loi du 6 janvier 1978 modifiée en 2004. Afin d'être conforme à la loi, vous êtes tenu de respecter tout au long de votre traitement les obligations prévues et notamment :

- 1) La définition et le respect de la finalité du traitement,
- 2) La pertinence des données traitées,
- 3) La conservation pendant une durée limitée des données,
- 4) La sécurité et la confidentialité des données,
- 5) Le respect des droits des intéressés : information sur leur droit d'accès, de rectification et d'opposition.

Pour plus de détails sur les obligations prévues par la loi « informatique et libertés », consultez le site internet de la CNIL : www.cnil.fr.

Organisme déclarant

Nom : GCS INST UNIVERSITAIRE CANCER ONCOPOLE

Service : IUCT ONCOPOLE

Adresse : 1 AVENUE IRENE JOLIOT-CURIE

Code postal : 31100

Ville : TOULOUSE

N° SIREN ou SIRET :

801812009 00018

Code NAF ou APE :

8610Z

Tél. : 08 92 97 70 56

Fax. :

Traitement déclaré

Finalité : MR3 - Recherches dans le domaine de la santé sans recueil du consentement

Transferts d'informations hors de l'Union européenne : Non

Fait à Paris, le 06 juillet 2017
Par délégation de la commission

Isabelle FALQUE PIERROTIN
Présidente

APPENDIX 4 - SOCIO-DEMOGRAPHIC CHARACTERISTICS OF GENERAL PRACTITIONERS

	Men (N=55)		Women (N=26)		Total (N=81)		
	M	(SD)	M	(SD)	M	(ET)	p
Age (years)	54.9	(10.2)	48	(9.3)	52.7	(10.4)	<0.01 ^W
Installation duration (years)	23.8	(11.6)	15	(8.3)	21	(11.3)	<0.01 ^W
	N	(%)	N	(%)	N	(%)	p
Location of practice:							
Rural	15	(27.3)	6	(23.0)	21	(25.9)	0.59 ^C
Semi-rural	25	(45.4)	10	(38.5)	35	(43.2)	
Urban	15	(27.3)	10	(38.5)	25	(30.9)	
Type of practice:							
Solo	16	(29.1)	5	(19.2)	21	(25.9)	0.34 ^C
Group + MSP	39	(70.9)	21	(80.8)	60	(74.1)	
Patient follow-up period:							
< 5 years	15	(27.3)	18	(69.2)	33	(40.7)	<0.01 ^C
> 5 years	40	(72.7)	8	(30.8)	48	(59.3)	
Doctors with training ¹ :							
Yes	4	(7.3)	1	(3.8)	5	(6.2)	1.00 ^F

¹ DU/DIU/Capacity/DESC: Palliative care, pain management, oncology
M = mean; SD = standard deviation; N = sample size; % = percentage
F = Fisher's test; ^C = Chi²-squared test; ^W = Wilcoxon-Mann-Whitney test; <0.05 = statistically significant result

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Organised breast cancer screening: the acceptability of a French decision-aid tool among women and Health professionals

INTRODUCTION

Breast cancer was the most commonly diagnosed cancer among women worldwide in 2022¹. In France, the organised breast cancer screening programme (Dépistage Organisé du Cancer du Sein, DOCS) follows WHO recommendations² by inviting women at moderate risk of breast cancer to undergo a bilateral mammogram every two years³. Participation rates in the DOCS remain below national targets, standing at 46.3% for 2023–2024, compared with a target of over 70 %. These rates appear to be declining compared with levels observed during the 2008–2015 period⁴. Following a public consultation⁵, during which many women expressed a need for clearer and more transparent information, the French health authorities recommend that women participating in the screening programme be provided with sufficient and appropriate information. They also recommend ensuring that women are able to make an informed choice as to whether or not to take part in screening^{1,6}.

Decision-aids (DA) have been developed to improve knowledge, reduce decision-making conflict and encourage people to make decisions consistent with their values. They can also facilitate shared decision-making⁷. Edwards et al. have defined international standards for assessing the quality of the aids on offer: they must be based on validated, up-to-date data, presented in a concise, illustrated and clear format, taking into account the expectations of the target population and the most appropriate methods of communication with patients^{8,9}. The effective use of a DA also depends on its acceptability to end users¹⁰. This acceptability depends on the length of the tool, the pace (in the case of an audiovisual tool), the amount of information provided and on the balanced presentation of the information¹¹. Receiving feedback from users is crucial and enables the DA to be refined¹².

In France, in the absence of such an aid meeting these standards, the National Cancer Institute launched a call for proposals with a view to developing a decision aid aimed at both women and healthcare professionals¹³. A prototype of the DA in the form of a website ('lamammo-etvous.fr') was developed in 2022¹⁴. It included written content, statistical data presented as infographics, and videos. The tool's five-part structure facilitated shared medical decision-making by highlighting a health issue, setting out the various available options along with

the advantages and disadvantages of each, and helping to identify the patient's values. The decision aid's development process followed international recommendations¹⁵ in three stages (Figure 1). The aid achieved the highest construction quality score on the International Patient Decision Aid Standards instrument (IPDASi) among international decision aids^{8,14,15} at the end of the first two stages of development (scope definition and design; alpha testing)¹⁴. Stage 3 assessing feasibility via beta testing remained to be carried out.

The primary objective of our study was to assess the acceptability of the decision aid relating to the DOCS amongst women and healthcare professionals involved in screening. The secondary objective was to measure the impact of the decision aid on women's knowledge, their decision-making conflict and their intention to participate in the DOCS.

METHOD

We conducted a survey of healthcare professionals and women to carry out the beta test of the DA. The study was conducted from March to November 2022 on the west coast of France.

Participants

A total of 50 healthcare professionals were approached based on their profession and roles within the DOCS. The study was presented at a meeting for general practitioners and midwives working in three multi-professional health centres (MSPs) in March 2022. The initial sample was supplemented by recruiting gynaecologists and midwives through random telephone calls, made using the French Health Insurance Directory (Ameli®).

Women eligible for this study were recruited from primary care settings. The study was presented and offered between April and October 2022 to 147 women in the waiting rooms of these three MSPs. (Appendix 1).

Development of the 'Acceptability' questionnaire for healthcare professionals

The 'Acceptability' questionnaire was based on previous work developed by the Ottawa Hospital Research Institute¹².

In Part A, seven closed-ended items focused on the presentation of the DA: layout of the information, amount of information, reading time, focus of the

messages, usefulness, understanding of the figures, and the value of the videos (Table 1). The response options were tailored to the content of the questions. Two open-ended questions sought general opinions on the website and suggestions for improvement.

In Part B, 14 items assessed healthcare professionals' perceptions of the use of the DA during consultations on a Likert scale ('Strongly disagree' to 'Strongly agree') (Appendix 2).

Five items collected information on the professionals' profiles (gender, age, profession, type of practice and place of practice).

Development of questionnaires for women

Pre-reading questionnaire on the DA

The pre-reading questionnaire assessed the potential impact of the DA on women using three scales (Appendix 3): 1) A scale measuring knowledge of the DOCS; 2) A scale measuring decision-making conflict (Decision Conflict Scale (DCS))¹⁶; 3) A scale measuring intention to participate in the DOCS¹⁷. The knowledge scale (18 items) was based on the items defined by the IPDAS (International Patient Decision Aid Standards) score¹⁸. The scale measuring decision conflict¹⁶ (10 items; response options: 'yes', 'I'm not sure', 'no') was designed for patients with low health literacy and had been validated in English¹⁹. Intention to participate was measured using a Likert scale ranging from 0 ('do not wish to participate in organised breast cancer screening') to 10 ('wish to participate in organised breast cancer screening')¹⁷.

The pre-reading questionnaire also collected data on the woman's age, her comfort with using the internet and whether she had previously had a mammogram (Appendix 4).

Post-reading questionnaire for the DA

The post-reading questionnaire assessed women's acceptance of the DA by asking them to answer the same items as in Part A of the questionnaire for healthcare professionals (Table 1). It also assessed the impact of the DA on women after they had read it, using the same three sub-scales as in the pre-reading questionnaire.

Administration of questionnaires and data collection

Participating healthcare professionals received an initial email introducing the study and including a link to the DA, followed three weeks later by a second email containing the link to the questionnaire, distributed via the LimeSurvey[®] platform, which centralised the responses. Follow-up reminders were sent by email or telephone where necessary. The women received an email describing the study along with the pre-test questionnaire (LimeSurvey[®] platform). Those who completed it received a link to access the DA, followed by a post-reading questionnaire three weeks later.

Data collection took place from March to June 2022 for healthcare professionals, and from May to November 2022 for women.

Outcome measures and data analysis

Continuous variables were described using the mean and standard deviation, and categorical variables using the number of cases and percentages for each category.

Measurement of the acceptability of the DA among healthcare professionals and women (primary outcome measure)

For closed-ended items, the acceptability of the DA was assessed by calculating the percentage of

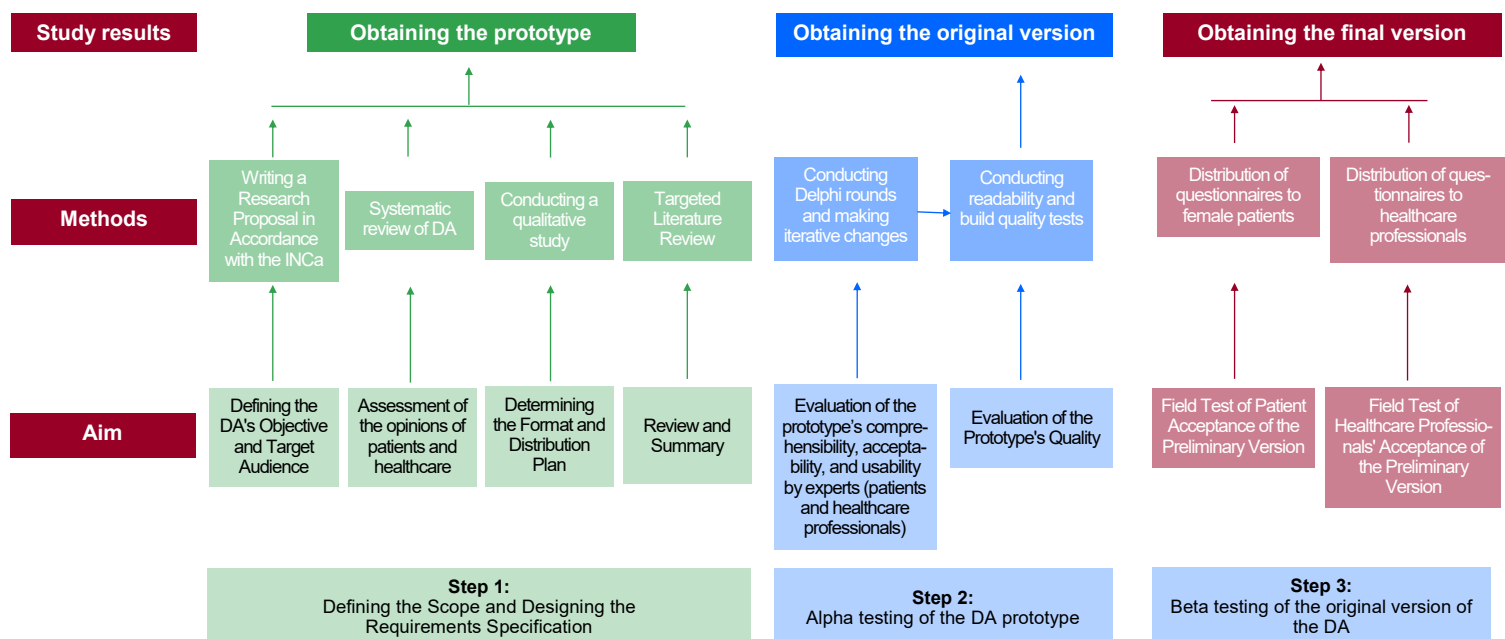


Figure 1 - Stages in the development of the decision-making out

responses in each category. A threshold of 50% favourable responses was expected (e.g. 'good' and 'excellent'; 'sufficient amount of information'; 'appropriate reading time', etc.). Responses to the questions from healthcare professionals and patients were compared using the Cochran-Armitage test for ordinal variables, or Fisher's exact test for categorical variables.

The responses provided by healthcare professionals and women to the open-ended items were analysed.

Measuring the impact of the DA on women (secondary outcome measures)

Knowledge score

The score on the knowledge questionnaire corresponded to the number of correct answers, with each item worth 1 point. For items 18a, 18b and 18c, which required a numerical estimate, an acceptable response range had been defined²⁰, and a response falling within this range was awarded 2 points (1 point was awarded for a response provided that fell outside the range). The accepted ranges were as follows: Q18a: [2–8], with the expected answer: 4; Q18b: [1–2], expected answer: 1; Q18c: [1–6], expected answer: 3 (Appendix 3). The maximum possible score was 23 points.

Measurement of decision conflict

The total decision-making conflict score was calculated by summing the points awarded for each item ('yes' (0 points), 'I'm not sure' (2 points) and 'no' (4 points))²¹. It could range from 0 to 40. A higher score indicated a greater level of decision-making conflict.

Intention to participate

The value used for intention to participate corresponded to the box ticked between 1 and 10¹⁷.

The various impact scores for the DA were compared before and after reading the DA using paired Student's t-tests. The alpha level was set at 5 per cent for two-tailed tests. The analyses were carried out using R software version 4.4.1 (R Foundation for Statistical Computing, Vienna, Austria).

Ethical considerations

Consent to participate in the study was obtained when the protocol was presented to healthcare professionals and women. Completing the questionnaire also constituted agreement to participate. Each participant was free to withdraw from the study at any time, without giving a reason.

The Ethics Committee for Non-Interventional Research at the University of Nantes (CERNI) issued a favourable opinion for the research on 3 December 2021 (patient component No. 0312021-1) and on 7 December 2021 (healthcare professionals component No. 07122021-1).

RESULTS

Participating healthcare professionals and women

Of the 50 healthcare professionals approached, 25 verbally agreed to take part. Of these, 18 (14 women, 4 men) completed the questionnaire. The mean age was 40.1 years (standard deviation = 8.9). Professions were distributed across general practice (n =

10), gynaecology (n = 2) and midwifery (n = 6). Three professionals practised in individual practice compared with 15 in group practices. Two practised in urban areas and 16 in rural areas.

Of the 147 women approached, 100 were included. Fifty-five completed both the pre- and post-reading questionnaires. The mean age was 60.4 years (standard deviation = 8.9) (Appendix 4). The majority had previously had a mammogram (98.2%). Most reported feeling comfortable using the internet (87.3%).

Acceptability of the DA's presentation and content among healthcare professionals and women (Table 1)

The DA was deemed 'useful' for deciding whether or not to take part in screening by 66.7% of healthcare professionals and 77.6% of women (Table 1). The expected threshold of 50% favourable responses was met for all items among healthcare professionals, and for six out of seven items among women (presentation of information for each group, amount of information, reading time, balance of information, usefulness, and assistance provided by the videos). The tables presenting quantitative data from the DOCS were perceived as difficult to understand by 54.2% of women.

Differences in perception between women and healthcare professionals concerned reading time and the perceived bias of the DA. Half of the healthcare professionals considered the reading time to be too long, compared with only 10.2% of women ($p < 0.001$). The information was perceived as discouraging screening by 38.9% of healthcare professionals, compared with 2.0% of women ($p < 0.001$) (Table 1).

Appendix 5 presents the responses to the open-ended questions. Participants appreciated the website's ease of use and the comprehensiveness of the information. Above all, they recommended it to women who were hesitant about or opposed to the DOCS. The use of an DA enabled women to consider participating in screening outside of the consultation.

Acceptability of the DA's use in consultations by healthcare professionals (Appendix 2)

The expected threshold of 50.0% of favourable responses was met for 10 of the 14 items. The DA was considered consistent with the vision of medicine by 68.75% of healthcare professionals, and complementary to their usual practice by 75.0%. For 75.0% of respondents, it enabled women to make more informed decisions; 75.0% felt that it helped them make a choice consistent with their values. Only 18.75% considered that its use would save time. Following the trial, 50.0% stated that they intended to continue using the DA in their practice.

Measuring the impact of the DA on women (Table 2)

Change in knowledge score

The average knowledge score among women increased significantly after reading the DA (10.15 vs 12.18; $p < 0.001$).

Measurement of decision-making conflict

A statistically significant decrease in the average decision-making conflict score among women was

		Number (%) of respondents (post-DA reading)		
PARTIE A		Healthcare Professionals (n = 18)	Women (n = 55)	p
1- What do you think of the way the information is presented in each section of the DA?				
DA Home Page				
Mediocre		0 (0,0 %)	0 (0,0 %)	0,595 ^a
Average		1 (5,6 %)	2 (4,1 %)	
Good		13 (72,2 %)	40 (81,6 %)	
Excellent		4 (22,2 %)	7 (14,3 %)	
Missing data		0	6	
“Am I Affected?” Section				
Mediocre		0 (0,0 %)	0 (0,0 %)	0,708 ^a
Average		2 (11,1 %)	4 (8,2 %)	
Good		10 (55,6 %)	33 (67,3 %)	
Excellent		6 (33,3 %)	12 (24,5 %)	
Missing data		0	6	
“Screening: Pros and Cons” section				
Mediocre		0 (0,0 %)	0 (0,0 %)	0,999 ^a
Average		5 (27,8 %)	7 (14,3 %)	
Good		8 (44,4 %)	35 (71,4 %)	
Excellent		5 (27,8 %)	7 (14,3 %)	
Missing data		0	6	
“My Preferences, My Concerns” Section				
Mediocre		0 (0,0 %)	0 (0,0 %)	0,705 ^a
Average		4 (22,2 %)	5 (10,2 %)	
Good		9 (50,0 %)	39 (79,6 %)	
Excellent		5 (27,8 %)	5 (10,2 %)	
Missing data		0	6	
“Preparing for My Consultation with My Healthcare Provider” Section				
Mediocre		0 (0,0 %)	0 (0,0 %)	0,206 ^a
Average		1 (5,6 %)	3 (6,1 %)	
Good		12 (66,7 %)	40 (81,6 %)	
Excellent		5 (27,8 %)	6 (12,2 %)	
Missing data		0	6	
Frequently Asked Questions				
Mediocre		0 (0,0 %)	0 (0,0 %)	0,097 ^a
Average		2 (11,1 %)	6 (12,2 %)	
Good		10 (55,6 %)	38 (77,6 %)	
Excellent		6 (33,3 %)	5 (10,2 %)	
Missing data		0	6	
2- What do you think of the amount of information in the DA?				
Not enough information		0 (0,0 %)	4 (8,2 %)	0,054 ^a
Sufficient information		14 (77,8 %)	41 (83,7 %)	
Too much information		4 (22,2 %)	4 (8,2 %)	
Missing data		0	6	
3- What do you think of the reading time for the DA?				
Too short		0 (0,0 %)	2 (4,1 %)	< 0,001 ^a
Adapted		9 (50,0 %)	42 (85,7 %)	
Too long		9 (50,0 %)	5 (10,2 %)	
Missing data		0	6	
4- Would you say that the DA is:				
Focused on non-participation in screening		7 (38,9 %)	1 (2,0 %)	< 0,001 ^a
Balanced		11 (61,1 %)	28 (57,1 %)	
Focused on participation in screening		0 (0,0 %)	20 (40,8 %)	
Missing data		0	6	
5- Do you find that the DA is useful as a decision-making tool regarding participation in organized breast cancer screening?				
Yes		12 (66,7 %)	38 (77,6 %)	0,364 ^b
No		6 (33,7 %)	11 (22,4 %)	
Missing data		0	6	
6- What do you think of the tables showing the figures by age group in the “Pros and Cons” section of the DA?				
The charts are easy to understand		11 (66,1 %)	22 (45,8 %)	0,408 ^b
Focused on participation in screening		7 (38,9 %)	26 (54,2 %)	
Missing data		0	7	
7- What do you think of the DA videos explaining the pros and cons of participating or not participating in organized breast cancer screening?				
Videos make it easier to understand		17 (94,4 %)	42 (85,7 %)	0,433 ^b
Videos make it harder to understand		1 (5,6 %)	7 (14,3 %)	
Missing data		0	6	

Table 1 - Acceptability of the presentation and content of the decision-making tool among healthcare professionals and women (Part A)

DA: Decision-Making Tool

^a Cochran-Armitage test

^b Fisher's Exact Test

	DAT pre-reading (n = 55)	DAT Post- readins (n = 55)	p ^a
Knowledge score			
	n = 55	n = 55	
Mean (standard deviation)	10,15 (1,98)	12,18 (3,54)	<0,001
Decision-Making Conflict			
	n = 53	n = 53	
Mean (standard deviation)	31,70 (26,75)	20,19 (23,18)	<0,001
Intention to participate			
	n = 54	n = 54	
Mean (standard deviation)	9,46 (1,65)	9,41 (1,82)	0,742

Table 2 - Measuring the Impact of the Decision-Making Tool on Women

observed after reading the website (20.19 vs 31.70; $p < 0.001$).

Intention to participate

The average score for intention to participate in screening fell from 9.46 before reading the DA to 9.41 after reading it ($p = 0.742$). No difference was observed in intention to participate before and after reading the website

DISCUSSION

Key findings

This study presents the beta test – the final phase of the development process – of the French digital health guide 'lamammo-etvous.fr': assessments of its acceptability by healthcare professionals and women, and of its impact on women's knowledge, their decision-making conflict, and their intention to participate in screening. Users appreciated the presentation of the digital health guide. The inclusion of video content facilitated understanding and retention of the messages. Healthcare professionals regarded the DA as complementary to their practice. Reading the DA significantly increased women's level of knowledge and reduced decision-making conflict, whilst no difference was observed in their motivation to participate in the DOCS, which was already present before reading. Women and healthcare professionals had differing perceptions of the focus of the DA's information and the time taken to read it.

Comparison of results with the literature

Several online DAs relating to breast cancer screening have been developed in recent years^{8,22-24}. The results concerning women's acceptance of the 'lamammo-etvous.fr' DA are similar to those reported in these studies in terms of clarity of information²³, amount of information^{8,22} and the perceived usefulness of the DA^{8,23}. The design of an DA must balance scientific rigour with clarity for users, ensuring the quality of the wording, the density of the information and the readability of visual aids²⁵.

The IPDAS guidelines emphasise the importance of presenting information both for and against participation in screening in a balanced manner¹⁸. Among women, our DA was predominantly perceived as balanced (57.1 per cent), although 40.8 per cent con-

sidered it to be biased in favour of screening. These results illustrate the difficulties frequently encountered in achieving a genuine balance in the information provided. The DA designed by Roberto et al., which was evaluated amongst a large sample of women ($n = 472$), was predominantly perceived as favouring screening (63.1%, compared with 36.9% who found it balanced and 0% who found it opposed to screening)²³. For their part, Schonberg et al. found a more mixed distribution ($n = 45$ women): their DA was perceived as both balanced (42.0%) and opposed to screening (42.0%), whilst 16.0% judged it to be in favour of screening⁸. The DA proposed by Riganti et al. showed a perceived balance of 100 per cent ($n = 11$ women)²⁴. With regard to healthcare professionals, Riganti et al.'s DA demonstrated a better balance of information than ours²⁴: 90.9% of the doctors surveyed ($n = 11$) perceived it as such, compared with 61.1% for our DA, whilst 38.9% considered our tool to be biased against screening.

The reduction in decision conflict and the increase in knowledge observed in our study following the use of the decision aid were consistent with those reported in the international literature^{26,27}. However, the impact on intention to participate appeared to vary more depending on the context. In Germany, Reder et al.²⁸ demonstrated, in a randomised controlled trial, a reduction in intention to participate (18.1% intention not to participate in the DA group versus 10.0% in the control group; $p = 0.007$). The French DECIDEO study observed a slight decrease in the breast cancer screening participation rate following the dispatch of an DA alongside the screening invitation (40.3% vs 42.1% in the control group, $p = 0.02$)²⁹. In contrast, in Spain, Perez-Lacasta et al.²⁷ observed, as in our study, that intention to participate in screening remained high and similar between the groups. More generally, a Cochrane review on DAs reported that, for several types of screening, DAs had no clear effect on intention or participation rates, and could in some cases such as breast or prostate cancer screening, lead to a decrease in actual participation⁶.

Strengths and weaknesses of the study

The development of the DA 'lamammo-etvous.fr' followed a rigorous approach in line with the recommendations of the IPDAS Collaboration¹¹. Its acceptability was assessed among women and healthcare professionals using a common questionnaire, yielding a very encouraging initial assessment. Although the sample size is modest, it remains comparable to that of similar studies reporting between 11 and 29 healthcare professionals²⁴ and 11 to 97 patients^{8,15,22,24}. The study relies predominantly on women who feel personally concerned by the subject and who have a DOCS participation rate above the national average. These characteristics suggest that the results should be interpreted with caution when extrapolating them to the non-participating population. The choice of the simplified 10-question version of the DCS, validated for populations with low literacy levels and adapted to our target population in primary care practices, must be taken into account when comparing our results with those of international studies. Furthermore, the assessment of knowledge was carried out using an unvalidated questionnaire, constituting a first step towards the

creation of a specifically validated tool for measuring knowledge of screening. Proposed items are set out in Appendix 3.

Perspectives

The research team concluded that the DA could be used in its current form, as the suggestions for improvement put forward by users and professionals were minor. However, to encourage its adoption, support for healthcare professionals remains necessary, particularly considering time constraints and doubts regarding its effectiveness compared with established standard practices³⁰. Designed to be consulted prior to the consultation, the DA thus minimises its impact on the duration of the consultation, whilst reinforcing patients' essential knowledge³¹. As information needs vary from person to person, the DA cannot replace a personalised discussion with a healthcare professional, who is able to tailor the information to

each patient's preferences and circumstances^{6,26,28}. An update to the data in the DA will be carried out shortly, incorporating, in particular, the concept of overall mortality³². Finally, a study is currently underway to examine the implementation of shared decision-making between healthcare professionals and patients using the DA³³.

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Abstract

Background. The decision-aid (lamammo-etvous.fr) was designed to support women's decision on whether or not to take part in organised breast cancer screening (DOCS) via mammography.

Objectives. To assess its acceptability among women and healthcare professionals. The secondary objective was to assess its impact on women's knowledge, decision-making conflict and intention to participate in DOCS.

Method. A cross-sectional survey involving a beta test of the DA, conducted in France in 2023 at three health centres. Healthcare professionals (general practitioners, midwives and gynaecologists) were involved. Women were invited to take part whilst waiting in the consultation room. The questionnaire for healthcare professionals assessed the acceptability and real-world use of the DA. The questionnaire for women assessed acceptability, level of knowledge, decision conflict (DCS-10) and intention to participate in the DOCS before and after reading the DA.

Results. 18 healthcare professionals and 55 women completed the questionnaires. Acceptability was good among both women and healthcare professionals. The tool was considered useful (66.7% of healthcare professionals and 77.6% of women), clear and relevant. Reading the DA significantly increased the women's level of knowledge (10.15 vs 12.18; $p < 0.001$), reduced decision-making conflict (20.19 vs 31.70; $p < 0.001$), and did not alter their motivation to participate in the DOCS (9.46 vs 9.41; $p = 0.742$). The evaluation revealed differences in perception between women and healthcare professionals: 50% of healthcare professionals considered the text too long, compared with only 10.2% of women ($p < 0.001$). The information was perceived as biased against the DOCS by 38.9% of healthcare professionals, compared with 2.0% of women ($p < 0.001$).

Conclusion. This acceptability study found that reading this DA, which was well-received by healthcare professionals and women alike, significantly increased women's level of knowledge, reduced decision-making conflict, and did not alter their motivation to participate in the DOCS. These findings will need to be confirmed by larger-scale studies.

Keywords: Breast cancer – Screening – Decision-making

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APPENDIX 1 - INCLUSION AND EXCLUSION CRITERIA FOR WOMEN AND HEALTHCARE PROFESSIONALS

	Women	Healthcare professionals
Inclusion criteria	Aged between 50 and 74	General practitioners, midwives, gynaecologists
		Working in outpatient settings
		Practising on the west coast of France
Exclusion criteria	Having a personal or family history of breast cancer with an Einsinger score of 3 or higher	Refusing to take part in the study
	Having difficulty understanding or speaking French	
	Having significant cognitive impairment	
	Refusal to participate in the study	

APPENDIX 2 - RESULTS OF HEALTHCARE PROFESSIONALS' PERCEPTIONS OF THE USE OF THE DAT DURING CONSULTATIONS (PART B)

PART B	Number (%) of respondents (post-DA reading)					
	Strongly disagree n (%)	Disagree n (%)	Neither agree nor disagree n (%)	Agree n (%)	Strongly agree n (%)	Missing data n
Q1. The website is easy to use	0 (0 %)	0 (0 %)	0 (0%)	10 (62.5%)	6 (37.5%)	2
Q2. The website is easy to understand	0 (0%)	1 (6.25%)	1 (6.25%)	8 (50.0%)	6 (37.5%)	2
Q3. Testing this site makes me want to keep using it	1 (6.25%)	3 (18.75%)	4 (25.0%)	4 (25.0%)	4 (25.0%)	2
Q4. The findings from using this website with my patient are easily observable.	1 (6.25%)	2 (12.5%)	4 (25.0%)	8 (50.0 %)	1 (6.25%)	2
Q5. The website is consistent with my view of medicine.	1 (6.25%)	1 (6.25%)	3 (18.75%)	7 (43.75%)	4 (25.0%)	2
Q6. Using this website is more effective than my usual practice in helping my patients make a choice.	1 (6.25%)	4 (25.0%)	5 (31.25%)	4 (25.0%)	2 (12.5%)	2
Q7. Compared with my usual practice, the website will enable my patients to make more informed decisions.	1 (6.25%)	2 (12.5%)	1 (6.25%)	10 (62.5%)	2 (12.5%)	2
Q8. Using this website will save me time.	2 (12.5%)	3 (18.75%)	8 (50.0%)	3 (18.75%)	0 (0%)	2
Q9. This website is a reliable way of helping patients make a decision about organised breast cancer screening.	2 (12.5%)	3 (18.75%)	5 (31.25%)	4 (25.0 %)	2 (12.5%)	2
Q10. The different sections of the website can be used independently of one another.	0 (0%)	1 (6.25%)	0 (0%)	11 (68.75%)	4 (25.0%)	2



PART B	Number (%) of respondents (post-DA reading)					
	Strongly disagree n (%)	Disagree n (%)	Neither agree nor disagree n (%)	Agree n (%)	Strongly agree n (%)	Missing data n
Q11. This type of website is suitable for helping patients make a choice that is consistent with their values.	0 (0%)	1 (6.25%)	3 (18.75%)	8 (50.0 %)	4 (25.0%)	2
Q12. This website complements my usual practice.	2 (12.5%)	1 (6.25%)	1 (6.25%)	10 (62.5%)	2 (12.5%)	2
Q13. Using this website will not lead to any major changes in the way I work.	1 (6.25%)	4 (25.0%)	3 (18.75%)	7 (43.75%)	1 (6.25%)	2
Q14. It is highly likely that using this website will bring more benefits than drawbacks.	1 (6.25%)	4 (25.0%)	4 (25.0%)	6 (37.5%)	1 (6.25%)	2

**APPENDIX 3 - QUESTIONNAIRE FOR WOMEN MEASURING
THE IMPACT OF THE DECISION-MAKING AID (3 SUB-SCALES)
SCALE MEASURING KNOWLEDGE OF THE DOCS**

	Suggested response options			Expected response	Future usefulness of the item	
					Useful item	Useless item
1. Breast cancer is the most common cancer in women.	True	False	I don't know	True	x	
2. Organised breast cancer screening is carried out even when I have no problems with my breasts.	True	False	I don't know	True	x	
3. The aim of organised breast cancer screening is to prevent the onset of breast cancer.	True	False	I don't know	False	x	
4. Organised breast cancer screening is offered to all women aged 50 to 74.	True	False	I don't know	False		x
5. As part of the organised breast cancer screening programme, a mammogram is reviewed by a single doctor.	True	False	I don't know	False	x	
6. As part of the organised screening programme, you need to pay for the mammogram up front, just as you would for a standard medical consultation.	True	False	I don't know	False		x
7. As part of the organised screening programme, the test carried out is a mammogram (X-ray).	True	False	I don't know	True	x	
8. Some women may find mammograms unpleasant.	True	False	I don't know	True		x
9. As part of the organised breast cancer screening programme, if my mammogram is normal, I will be offered a repeat mammogram every two years until I am 74.	True	False	I don't know	True		x
10. If the mammogram is abnormal, I may be offered one or more further tests to find out if there is cancer; which ones? (Multiple answers possible) [Another mammogram]	True	False	I don't know	True for ultrasound, MRI, biopsy False for a CT scan		x

	Suggested response options			Expected response	Future usefulness of the item	
					Useful item	Useless item
11. If cancer is detected as part of the organised breast cancer screening programme, I am more likely to have a small tumour and to require less invasive surgery.	True	False	I don't know	True	x	
12. I have the choice to take part in the organised breast cancer screening programme.	True	False	I don't know	True		x
13. Organised breast cancer screening can detect all cases of breast cancer.	True	False	I don't know	False	x	
14. All women who have an abnormal mammogram have breast cancer.	True	False	I don't know	False	x	
15. Screening can detect a cancer that would never have progressed or caused any problems in daily life.	True	False	I don't know	True	x	
16. Scientific evidence shows that the risk of dying from breast cancer is lower when you take part in organised breast cancer screening.	True	False	I don't know	True		x
17. Organised screening may lead some women with cancer to receive treatment even though it is not known whether the cancer would have been life-threatening.	True	False	I don't know	True	x	
18. For the next three questions, imagine 1,000 women aged between 50 and 59 taking part in the organised breast cancer screening programme.						x
a) Of these 1,000 women aged between 50 and 59 who are taking part in the organised breast cancer screening programme, over a period of 7 years, approximately how many will die from breast cancer?	Given figure			Expected 4 Accepted [2–8]		
b) Of these 1,000 women aged 50 to 59 who take part in organised breast cancer screening over a 7-year period, how many deaths from breast cancer will be prevented?	Figure			Expected 1 Accepted [1–2]		
c) Of these 1,000 women aged 50 to 59 who take part in organised breast cancer screening over a 7-year period, approximately how many will be diagnosed, monitored or treated for breast cancer that would not have caused any problems (overdiagnosis)?	Figure			Expected 3 Accepted [1–6]		

SCALE MEASURING DECISION CONFLICT

	Proposed response options		
1-Are you aware of the options regarding organised breast cancer screening?	Yes	I'm not sure	No
2-Are you aware of the benefits of each option (i.e. taking part in or not taking part in organised breast cancer screening)?	Yes	I'm not sure	No
3-Are you aware of the risks and side effects of each option (i.e. taking part in or not taking part in organised breast cancer screening)?	Yes	I'm not sure	No
4-Are you sure which benefits matter most to you when it comes to this choice?	Yes	I'm not sure	No
5-Are you sure which risks and side effects matter most to you when it comes to this choice?	Yes	I'm not sure	No
6-Do you have enough support from others to make a choice?	Yes	I'm not sure	no
7-Do you make your choice without pressure from others?	Yes	I'm not sure	No
8-Do you have enough advice to help you make a choice?	Yes	I'm not sure	No
9-Are you sure which is the best choice for you?	Yes	I'm not sure	No
10-Are you sure about the choice you're going to make?	Yes	I'm not sure	No

SCALE MEASURING INTENTION TO PARTICIPATE

If your doctor asked for your opinion on taking part in organised breast cancer screening, please indicate where you would place yourself on the scale below. How likely are you to take part in organised screening?



**I do not wish to take
part in breast cancer
screening**

**I would like to take
part in breast cancer
screening**

APPENDIX 4 - CHARACTERISTICS OF THE WOMEN TAKING PART IN THE STUDY

	Women (n = 55)
Age, years	
Mean (standard deviation)	60.4 (6.3)
50 to 59	23 (41.8%)
60 to 69	26 (47.3%)
70 to 74	6 (10.9%)
Previous mammogram	
No	1 (1.8%)
Yes	54 (98.2%)
In response to a screening invitation by post	46 (85.2%)
Other	18 (33.3%)
Comfort with using the internet	
No	7 (12.7%)
Yes	48 (87.3%)

APPENDIX 5 - ACCEPTABILITY OF THE PRESENTATION AND CONTENT OF THE DECISION-AID TOOL AMONG HEALTHCARE PROFESSIONALS AND WOMEN (SUMMARY OF RESPONSES TO THE OPEN-ENDED QUESTIONS IN PART A).

Respondents praised the visual presentation of the website, referring to 'soft colours' (SF2), a 'pleasant' interface (Woman, open-ended comments), and illustrations deemed 'appropriate' and 'inclusive' (MG2). Both groups found the navigation intuitive. Healthcare professionals highlighted "ease of use" and "easy-to-recognise tabs" (MG2), whilst women emphasised how "easy it was to move from one piece of information to another" (Woman, open-ended comments).

The content of the DA was largely perceived as clear, accessible and transparent. Healthcare professionals highlighted the 'relevance' (MG2), 'transparency' (MG4) and 'adequacy' (SF6) of the information, as well as its suitability for addressing 'patients' queries' (MG1). Women mentioned the "simplicity of the explanations", the "thoughtfulness of the information" and the fact that they were "finally receiving comprehensive information", particularly regarding the drawbacks of screening: "For once, we're being given comprehensive information; they don't hesitate to highlight the negative aspects of screening. I appreciate this candour" (open-ended comments).

Healthcare professionals and women agree on the DA's role in facilitating the decision-making process. It allows people to 'think things through at home' (MG2), to 'gather information to discuss with a healthcare professional' (G1), and promotes shared decision-making: "An essential tool for shared decision-making" (MG5), "It helped me make my decision" (open-ended comments), "I feel more involved in my decision-making" (open-ended comments).

The summary sheet was appreciated by both groups: "A valuable tool for shared decision-making" (MG10), "Made it easier to discuss things with the healthcare professional during the consultation" (open-ended comments). The issue of the readability of the tables containing figures was raised: "The tables are clear, but I'm not sure if they're meaningful to patients" (G1). Specific suggestions were put forward: creating "shorter tabs, without cutting out any information" (MG2), and using videos to aid understanding. Respondents emphasised the value of making the DA accessible from the moment the screening invitation is sent out. The women suggested tailoring the dissemination of information to different demographics: "Younger generations will appreciate being able to access information online. For those aged 70 and over, [...] we need to find a way to raise their awareness" (open-ended comments).



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Body image and oral contraception: women's experiences

INTRODUCTION

In 2016, the oral contraceptive (OC) was the most widely used method of contraception in France, used by 36.5 per cent of women¹. In 2019, 23 per cent of women aged 20 to 24 on low incomes used the OC, compared with 38 per cent of those on medium or high incomes². This predominance of OC use has led to the concept of a stereotypical contraceptive pathway: GPs would respond to an initial request for contraception by prescribing OC as the first-line treatment³. This prescribing practice could be explained by established habits, fears of adverse effects associated with other contraceptives, and a lack of confidence in performing the procedures required to insert intrauterine devices or contraceptive implants⁴. Women also contributed to this stereotypical contraceptive pathway by describing the CO as the method they were seeking, expected to use, and expected to be prescribed⁵.

Taking the CO appeared to be experienced by women as a constraint, imposing a mental burden⁶. Weight gain whilst on CO was also described by women as a burden⁵. Data from two meta-analyses conducted in 2014 and 2016 did not appear to establish a statistically significant link between oestrogen-progestogen or progestogen-only contraception and weight gain^{7,8}. However, weight gain was regarded by women as an adverse effect of the CO and could even prompt them to stop taking it^{5,9-13}. To encourage continued use of contraception, studies have suggested discussing the adverse effects of contraceptive methods with women and their partners at the time of prescription, by addressing the concerns they expressed, such as weight^{11,13}.

An influence of CO on body image has been described in the literature, with greater attention being paid to appearance among women using hormonal contraceptives. Longer duration of use appeared to be significantly associated with greater body monitoring and the adoption of weight-control behaviours that are more harmful to health¹⁴. Body dissatisfaction was associated with, and even predictive of, low self-esteem, emotional distress, depression or social anxiety. Body dissatisfaction was also associated with health-risk behaviours (unprotected sex, taking up smoking). Promoting a positive body image during adolescence could act as a protective factor against certain risky behaviours. This approach required adaptation to women's cultural context¹⁵. The body ideal sought by an individual is linked to the socio-

cultural context and societal ideals¹⁶. Body dissatisfaction also appeared to influence sexual health. In women, it has been described as negatively correlated with their partner's sexual and marital satisfaction¹⁷. Social pressure exerted on women regarding their body image, particularly via social media, could also be a cause of body dissatisfaction and a tendency towards thinness¹⁸. Stereotypical contraceptive practices and societal body norms may contribute to body dissatisfaction. The use of hormonal contraceptives appeared to influence concerns relating to body image, but what exactly is the role of the experience of hormonal contraception in body dissatisfaction?

The aim of this study was to explore women's experiences of CO in relation to body image.

METHOD

A qualitative study based on Pierce's pragmatic phenomenological approach, using open-ended individual interviews, was conducted between September 2023 and December 2024. This approach was chosen to explore the women's lived experiences and analyse them through Peirce's categories: Firstness, Secondness and Thirdness^{19,20}. This study was conducted by two researchers (RF, a postgraduate student in general practice and CP, a general practitioner and lecturer in general practice).

Study population

Women of legal age currently taking or who had previously taken the contraceptive pill were recruited during general practice consultations by the researchers and via leaflets displayed in the waiting room (Appendix 1 online). The sample was targeted and homogeneous in terms of experience (pill use) but varied in terms of age and socio-occupational category.

Data collection

The interview guide was structured around open-ended questions to explore various dimensions of the experience: the emotional and physical relationship with oral contraceptives, the relationship with one's own body, the relationship with others and with sexuality, and the day-to-day experience of taking contraception. A logbook documented the evolution of successive versions of the guide in terms of follow-up questions. Follow-up questions regarding the contraceptive journey were removed –

for example, a question about the first oral contraceptive prescription – as the responses strayed from the study's objective. The logbook also enabled the researchers to challenge their preconceptions, which were that the experience of taking oral contraceptives was characterised by body dissatisfaction. The interviews were conducted by a researcher (RF). The location of the interviews was left to the discretion of the women interviewed. They were conducted in person or via videoconference, depending on the women's availability, using Apple FaceTime® or WhatsApp® video calls. The interviews were recorded, transcribed in full and anonymised using Microsoft Word®.

Data analysis

The analysis was carried out using Microsoft Word® software by RF and CP. An independent analysis of each interview was conducted, categorising themes based on C.S. Peirce's semiotics and linking them to 'primacy', which corresponded to women's perception of their body image independently of the CO, secondaryness, which corresponded to the perception of body image in relation to the CO; and tertiaryness, which corresponded to the integration of women's perception of their body image in relation to the CO within their interactions with their environment. The theoretical adequacy of the data was confirmed by the completion of the final two interviews.

Ethical and regulatory aspects

This study was declared to the French Data Protection Authority (Commission nationale de l'informatique et des libertés) and was approved by the Ethics Committee of the Saint-Étienne University Hospital Centre on 4 September 2023 under reference number IRBN992023/CHUSTE (Appendix 2 online). Consent was obtained from the women participating in the study prior to the recording of the interviews, based on the information and consent forms (Appendix 3 online).

RESULTS

Thirteen individual interviews, lasting an average of 25 minutes, were conducted with women aged between 23 and 44 who were currently on the contraceptive pill or had previously been on it (Table 1). A summary of the results based on Peirce's categories is illustrated in Figure 1.

A body image shaped by the desire to please

The women emphasised the importance of body image, particularly during adolescence, 'at that age when you're building a self-image' (E13), driven by a desire to please: 'we started wanting to be beautiful, wanting to please so we could have a boyfriend' (E9, 13). The views of others were important, with the need to 'project a good image' (E1, 5). The desire to please could, moreover, be reinforced during periods of singlehood (E1).

There was a link to being slim: 'to be attractive, you had to be slim' (E7, 9), and to conform to 'a very slim ideal' (E1). Skin condition also influenced body image, particularly in relation to acne (E13).

Social media had an impact on body image and encouraged comparison: 'you see women who seem perfect, with ideal bodies', 'slim in swimsuits', 'it reinforces the feeling of injustice. It makes you want to look like them, and you end up comparing

yourself' (E1,7).

Some women felt comfortable with their bodies: 'I loved my body', even feeling 'lucky to feel good' and without any insecurities (E10, 13). This positive body image had a positive impact on relationships: 'I was pretty; things went well with boys' (E13). A certain neutrality could be described in terms of body image as 'a fairly neutral relationship with my body' (E11).

The CO: a reassuring, logical, even normative solution, but one met with some reluctance

Considered for its contraceptive effect or to treat acne, it could seem like a suitable or even reassuring solution: 'I wasn't ready to try anything else', 'I really needed some reassurance' (E2, 6–8, 12). Taking the CO could reduce anxiety linked to the risk of pregnancy (E1, 12).

Peer pressure could influence the decision to take the CO: 'All my friends were on the pill, so I followed suit' (E6), 'under pressure from my mum' (E10). Taking the pill was seen as a logical next step or even the norm: 'It was the right thing to do, so I took it without asking too many questions' (E10,11,13).

Some women expressed reservations: 'I don't want to take hormones for no reason', coupled with a fear of the impact on their bodies: 'It's a hormonal treatment, so I felt as though I had a foreign substance inside me that was going to throw my body out of balance' (E5,6). Once oral contraception had begun, a need to 'get my body back to its natural state' was described (E13).

An experience influenced by the effects of oral contraception: self-control, relationships with others and sexuality

Malaise, loss of confidence, guilt, loss of control over one's body and relationships

Oral contraception could be 'catastrophic for my body image', leading to weight gain or acne (E1-5-13). This effect could be mitigated by other factors such as age, a life event (moving house), or lifestyle: stress, diet, physical activity (E1,3,4,6,7). A feeling of unease was sometimes described in connection with physical changes: 'Psychologically, it was difficult to accept, because I wasn't ready to see my body change so much' (E5, 7, 13). A loss of self-confidence was described (E6,7,13), as well as a feeling of losing control: 'Every time I saw a new breakout or had to buy clothes a size bigger, I felt as though I was losing control of my body' (E13). This loss of control could extend to emotions: 'I was extremely fragile, extremely impulsive; I'd fly off the handle at the slightest provocation, and when I cried, I felt as though I couldn't stop' (E1, 3, 7). Reactions to physical changes could be as extreme as shock (E7). Looking in the mirror was difficult, with the feeling of not recognising oneself: 'I'd look at myself in the mirror and I no longer recognised my body' (E5, 7, 13). The way others looked at them (parents and social media) could reinforce these negative feelings (E5, 7). It might also have no impact at all (E6). Seeing other, slimmer women could intensify a sense of unease and lead to feelings of low self-esteem and sadness, even guilt: 'When I saw other women, all slim and pretty, I felt uncomfortable, and I told myself that my partner must surely find them more attractive than me. I felt sad that he was with such a fat woman; he didn't deserve

Interviews	Age (years)	Marital status	Occupation	Current contraception	Duration of contraceptive use	Date of discontinuation of CO	Location of the interview	Duration (min)
E1	23	In a relationship, no children	Midwife	Hormonal IUD	4 years	Since 6 months	Home	35
E2	23	In a relationship, no children	Teaching assistant	Copper IUD	7 years	Since 6 months	Video conference	14
E3	23	In a civil partnership, no children	IT project manager	Postgraduate Diploma in Endocrinology	6 and a half years	Since 2 weeks	Home	15
E4	26	Single, no children	Executive secretary	None	3 years	Since 2 years	Video conferencing	25
E5	25	Single, no children	Care assistant	None	A few months	A few months	Doctor's surgery	11
E6	35	Married, 1 child	Dietitian	None	18 years	Since 11 months (pregnancy)	Doctor's surgery	17
E7	26	In a civil partnership, no children	Laboratory technician	None	9 years	Since 3 years	Doctor's surgery	30
E8	31	In a relationship, 1 child	Unemployed	CO	7 years	Ongoing	Doctor's surgery	27
E9	28	Couple, no children	Head of Communications	None	7 years	Since 7 years	Place of residence	30
E10	36	Married, 2 children	Nurse	CO	18 years	Currently studying	Home	23
E11	40	Married, 2 children	Dentist	Subcutaneous implant	10 years	Since 11 years	Video conference	27
E12	41	Married, 1 child	Engineer	CO	20 years	In progress	Video conference	35
E13	44	Divorced, 2 children	Ready-to-wear manager	Copper IUD	22 years	Since 4 years	Video conference	36

Table 1 – Characteristics of the women surveyed
Key: IUD: intrauterine device; OC: oral contraception

that" (E7).

Sexual life could be affected by feelings of unease: "What comes into play when it comes to sexuality is, once again, body image; there were times when I didn't necessarily feel good about myself when I'd put on weight" (E1,6). Some women might feel less desirable: "When I was on the pill, my sex life was quite complicated. Because of the acne and weight gain, I didn't feel attractive" (E1,13). Sexual desire could remain intact (E1-3,5,13). A decrease in libido was sometimes described, with the body becoming a source of self-consciousness that was difficult to reveal: "As well as the decrease in libido, my body had become a real source of self-consciousness. I no longer liked showing myself off, whether in private, on the beach or at the swimming pool" (E4,7). Contraceptive use could have an impact on the relationship, leading to a distancing "I often felt uncomfort-

table showing myself naked, and that created a sort of distance'—sometimes leading to a break-up—"my first partner left me, so I told myself it was because of my weight gain; I blamed the pill, telling myself it must have had an effect on my love life because I was less pretty" (E5,6,13).

Well-being, freedom and control over one's body and relationships

Some women described little or no impact of the CO on their body image: "I've never had any major issues with my body because of the pill", "my body hadn't really changed with or without it" (E8,10-12). The CO could even improve body image by stabilising weight or preventing acne and the associated insecurities (E8,10-12). The CO could help women to 'love my body more' (E11). This positive body image could be linked to a sense of well-being

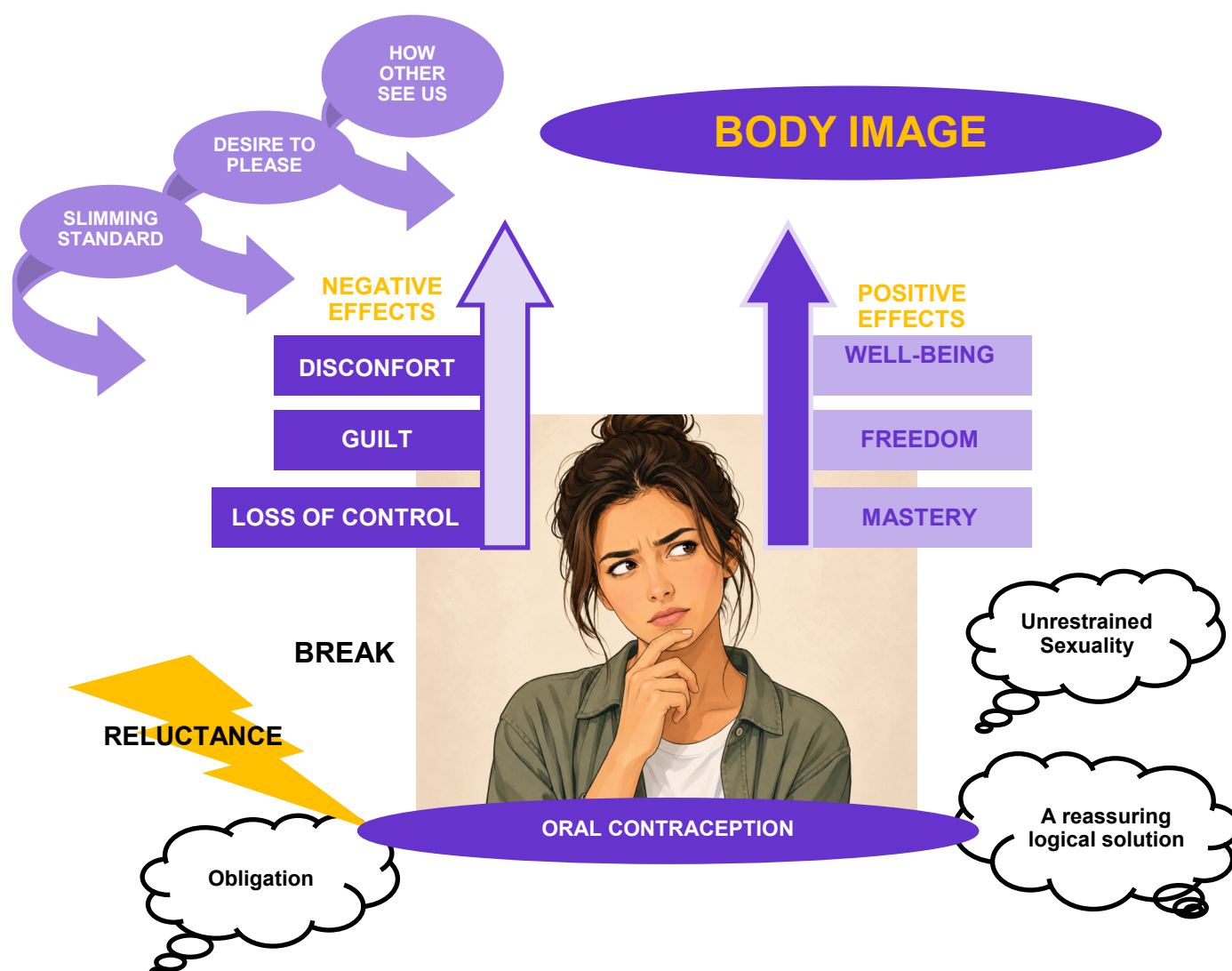


Figure 1 - Summary of the results on body image and oral contraception

(E10,11). An improvement in self-confidence was also described: 'these small positive changes helped me to accept myself better' (E11).

Physical changes could be positive for the woman and her relationship: 'I went up a bra size, from a B to a C, and I was delighted; I felt more feminine. My boyfriend at the time was also very pleased, so that was a positive side effect!' (E11).

Taking the contraceptive pill could also have a positive impact on sexuality, bringing a sense of relaxation: "The pill allowed me to be much more relaxed about my sexuality" (E8,10,11). The contraceptive pill might have no impact on libido or might increase it thanks to the feeling of protection: "I had a normal libido. Perhaps even a little higher, since I knew I was protected against the risk of pregnancy" (E9,12). A sense of freedom could be linked to a sense of serenity: "Above all, the pill helped me feel freer and more at ease with my sexuality", even leading to "a more uninhibited sex life" (E9,10). Physical satisfaction linked to taking the CO also involved a reduction in inhibitions in intimate situations: "I no longer felt as self-conscious about being naked" (E12).

The importance of personalised support from

healthcare professionals

A lack of personalised information was highlighted: 'Doctors don't tell you about all the options available that might be more suitable' (E6). Regret that another method of contraception had not been prescribed was linked to a feeling of being misunderstood: 'It's a shame that some people don't respect a person's choice; after all, it's my body' (E1), "My doctor at the time was really against the coil" (E7). This lack of understanding could go as far as giving the impression of mockery and of the effects being downplayed or denied: 'I found it even harder to cope with the fact that I wasn't being listened to on these issues; I almost felt as though I was being mocked by some healthcare professionals, as if these problems weren't important', 'He played it down, saying it was only temporary or that I should pay more attention to my diet' (E13), "Most people will say it's not the pill that makes you put on weight" (E1). These attitudes could lead to a feeling of isolation: "I felt very alone with these problems" (E13).

DISCUSSION



Summary of the main findings: An experience influenced by the effects of CO on body image: between loss and regain of control

The development of body image was shaped from adolescence onwards by the desire to please, the ideal of thinness and the influence of others' perceptions, particularly via social media. CO initially appeared to be a reassuring, logical and even normative solution, albeit one met with some reluctance. The women's experience was influenced by the effects of CO on body image. The negative effects of CO were associated with feelings of unease, guilt, loss of confidence and control over one's body, and in relationships, even leading to break-ups. Friends, family and healthcare professionals could contribute to these negative feelings. The positive effects of OC were associated with feelings of well-being, freedom and a sense of control over one's body and in relationships, extending to a more 'uninhibited' sexuality.

Comparison with the literature

The development of early body image has been identified in the literature as being influenced by peers, physical activity, the media and the school environment²¹. Adolescents attempt to meet beauty standards and societal expectations²¹. The ideal of thinness has also been identified in the literature; the more one compares oneself to others, the greater the internalisation of social ideals regarding physical appearance and the greater the body dissatisfaction²². Social media appeared to increase social comparisons and lead to a heightened awareness of the side effects of CO, with an impact on well-being^{21,23}.

The sense of unease described by women could be exacerbated by those around them or by healthcare professionals. Discrimination linked to weight gain or being overweight has also been described in the literature²⁴. The downplaying of women's suffering by healthcare professionals could also increase their sense of unease²⁵. By denying the effects described by women or dismissing them as normal, healthcare professionals took the view that women simply had to put up with them, thereby placing the onus of responsibility on the women themselves²⁵. There were even reports of efforts to downplay the effects on body image²⁶. This attitude could lead healthcare professionals to make hurtful remarks: 'Contraception makes you hungry, but it doesn't make you put on weight. It's not the pill that opens the fridge door!' To combat this kind of behaviour, it has been suggested that consultations should be conducted in accordance with the four principles of bioethics: autonomy, beneficence, non-maleficence and justice²⁵.

This unease could give rise to a sense of guilt, which has also been described in the literature in cases of weight gain²⁴. Attributing physical changes such as weight gain to CO might enable women to

explain them²⁷. It might also serve as a means of combating the sense of guilt associated with physical changes through a process of 'exculpation'. Identifying this process could help to improve the relational approach²⁸.

The effects of CO on body image could influence not only the individual's experience but also their relationships with others, particularly intimate ones. Positive effects of CO on body image, such as a reduction in insecurities, had a beneficial impact on sexual life. A sense of relaxation linked to protection against the risk of pregnancy was described in this study. This sense of serenity was associated with a feeling of freedom that could extend to a more 'uninhibited' sexuality. In the literature, women appeared to be more receptive to sexual cues once protected from the risk of pregnancy²⁹. This was also associated with greater sexual satisfaction was also associated with this²⁹. The CO could improve libido and arousal within the couple, given the absence of fear of an unwanted pregnancy, gynaecological symptoms (dyspareunia or dysmenorrhoea), or body image issues, with less acne and hirsutism³⁰.

Some women interviewed described a negative impact of CO on their sexuality, linked to a negative body image and insecurities. In the literature, sexual problems and dysfunctions appeared to be more common with hormonal contraception, but the use of combined CO was not a direct factor³¹. The partner's attitudes towards sexuality and the level of anxiety appeared to be key factors influencing sexual function³¹. The authors suggested that these factors be assessed when prescribing³¹.

Strengths and limitations

The originality of this study was a strength, as its aim was to explore women's experiences of body image whilst on COs using Pierce's pragmatic phenomenological analysis. Adherence to the COREQ³² criteria ensured methodological rigour and enabled the model to be developed by several researchers. Conducting interviews via video-calls may constitute a limitation, but the women's choice of interview location may have helped to create the most conducive atmosphere for exploring aspects related to their experience in depth. The interviews were conducted by RF, who was inexperienced; the first few interviews were brief due to a lack of follow-up questions, but their quality improved as the interviews progressed. His status as a GP trainee might suggest a social desirability bias, but his approach as a researcher helped to minimise this phenomenon. It might have been interesting to interview more women on low incomes, even though they appear to be less likely to choose CO than women on higher incomes².

Abstract

Introduction. In 2016, oral contraception (OC) was the most widely used contraceptive method in France, within a context of stereotypical contraceptive practices. This, combined with societal norms, may have contributed to body dissatisfaction. The use of hormonal contraceptives appeared to influence concerns relating to body image.

Objective. To explore women's experiences of OC in terms of body image.

Method. Pierce's pragmatic phenomenological approach, using individual open-ended interviews based on Peirce's categories of primacy, secondaryness and tertiaryness, in accordance with the COREQ 32 criteria.

Results. Thirteen interviews were conducted with women currently using, or who had previously used, CO. The development of body image was marked from adolescence onwards by the desire to please, the norm of thinness and the influence of others' perceptions, particularly via social media. CO initially appeared to be a reassuring, logical, even normative solution, albeit one met with some reluctance. The women's experiences were influenced by the effects of CO on body image. The negative effects of CO were associated with feelings of unease, guilt, loss of confidence and control over one's body, and difficulties in relationships, including break-ups. Friends, family and healthcare professionals could contribute to these negative feelings. The positive effects of CO were associated with feelings of well-being, freedom and a sense of control over one's body and in relationships, extending to a more 'uninhibited' sexuality.

Conclusion. Exploring the bodily experiences of women on oral contraceptives may enable us to better understand and support them by systematically incorporating the sexual dimension into contraceptive consultations and by avoiding attitudes that downplay the effects experienced by women – which can be intense – and reinforce the burden of contraceptive responsibility placed on women.

Keywords: oral contraceptives – body image – sexuality – qualitative research.

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APPENDIX 1 - INFORMATIONAL POSTER FOR THE WAITING ROOM

Would you like to share your thoughts?

As part of my thesis in general practice, I'd like to invite you to share your thoughts during an interview, which can take place at my office, at any other location convenient for you, or via videoconference. It will last less than an hour.

The purpose of this interview is to explore your experience as a user of oral contraceptives and your feelings, particularly regarding body image.

The data will be anonymized and will not affect your medical record.

If you'd like to participate, please let your primary care physician know during your next appointment so that we can get in touch with you.

Thank you in advance for your attention to this poster.

Rémi Flores

APPENDIX 2 - ETHICS COMMITTEE APPROVAL



Comité d'Éthique du CHU de Saint-Etienne
Commission recherche de Terre d'éthique
comite.ethique@chu-st-etienne.fr
Pr Pascale Vassal
pascale.vassal@chu-st-etienne.fr
Institutional Review Board : IORG0007394

Saint-Etienne, le lundi 4 septembre 2023

De : Pascale Vassal

Réf: **IRBN992023/CHUSTE**

Objet : **Avis Favorable**

Titre : « Contraception orale et prise de poids : l'expérience des femmes. »

Madame, Monsieur,

Je vous remercie d'avoir soumis votre projet de recherche au Comité d'Éthique du Centre Hospitalier Universitaire de Saint-Etienne.

Cette étude a été examinée lors de la séance plénière du mercredi 30 août 2023. Un résumé a été présenté par M. Rémi FLORES qui a par la suite répondu aux questions des membres du Comité d'Éthique.

Votre projet a été référencé par le numéro IRBN992023/CHUSTE.

Nous vous demandons de faire référence à ces numéros dans tous les documents qui seront produits ainsi que pour toutes correspondances.

Au regard de l'article R1121-2 du code de la Santé Publique modifié par Décret n°2006-477 du 26 avril 2006 - art. 1 JORF 27 avril 2006 définissant dans son alinéa 2 et suivants « les recherches non interventionnelles portant sur des produits mentionnés à l'article L.5311-1 » et du code Pénal article 226-16 et suivants relatifs « aux atteintes aux droits de la personne résultant des fichiers ou des traitements informatiques », le Comité d'Éthique du CHU de Saint-Etienne a examiné les pièces et auditionné le représentant de ce projet de recherche.

Après délibération, le Comité d'Éthique du CHU de Saint-Etienne a donné un **Avis Favorable** à la conduite de cette étude.

Si votre projet change après la date de cet avis sous quelque forme que ce soit, vous devez en informer le Comité d'Éthique.

Très cordialement

Professeur Pascale VASSAL



M. Rémi FLORES
Dr Catherine PLOTTON

Campus Santé Innovations
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APPENDIX 3 - INFORMED CONSENT FORM



Contraception orale : l'expérience des femmes en termes d'image corporelle
Version n°1 du 16/03/2023

Notice d'information du patient.

Coordonnées de l'investigateur coordonnateur (responsable du traitement des données et de la recherche)

Nom Flores Rémi

Coordonnées du Délégué à la Protection des Données

Pour le CHU

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Pour l'Université

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Saint-Étienne

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Madame,

La contraception orale ou pilule est le moyen de contraception le plus utilisé par les femmes en France.

1. Cette étude vise à explorer l'expérience des femmes majeures qui utilisent ou ont utilisé une contraception orale ou pilule notamment en termes d'image corporelle.

Si vous acceptez de participer à cette étude, je vous rencontrerai pour un entretien qui se tiendra dans le lieu de votre choix (domicile, cabinet médical ou autre). Il durera entre 30 minutes et 1 heure maximum. Les informations seront recueillies par enregistrement audio et seront rendues anonymes. Ces enregistrements seront retranscrits par écrit.

Votre participation n'est pas obligatoire, et n'aura pas d'impact sur votre suivi médical.

Dans le cadre de cette recherche, un traitement informatique de vos données personnelles va être mis en œuvre afin de pouvoir répondre aux objectifs scientifiques de cette recherche, dans une finalité d'intérêt public. Dans ce but, les données médicales vous concernant *et, dans la mesure où ces données sont nécessaires à la recherche, vos habitudes de vie, vos origines ethniques ou des données relatives à votre vie sexuelle ou à votre religion*, seront transmises au promoteur de la recherche ou aux personnes agissant pour son compte, en France. Ces données seront identifiées par un numéro ainsi qu'un code fait de la 1^{ère} lettre de votre nom et de votre prénom. Ces données pourront également, dans des conditions expérimentales assurant leur confidentialité, être transmises aux autorités de santé françaises, à d'autres

services de l'Université de Saint-Étienne

Conformément au Règlement Européen n°2016/679 sur la Protection des Données, vous pouvez :

- demander à avoir accès, à rectifier, à recevoir sous un format lisible numériquement ou à effacer les données vous concernant
- vous opposez au recueil et à la transmission de vos données ou limiter l'utilisation de vos données uniquement à cette étude ou à d'autres situations précises
- en cas de désaccord, procéder à une réclamation auprès de la Commission Nationale de de l'Informatique et des Libertés, 3 Place de Fontenoy - TSA 80715 - 75334 PARIS ou sur <https://www.cnil.fr/webform/adresser-une-plainte>

Vos données seront conservées jusqu'à la rédaction du rapport final de la recherche. Elles seront ensuite archivées durant 15 ans (comme pour les recherches hors produits de santé impliquant la personne humaine).

Vous êtes libre de refuser ou d'interrompre votre participation à cette étude à tout moment sans encourir aucune responsabilité ni aucun préjudice de ce fait et sans avoir à vous justifier.

Votre décision d'opposition ou de non opposition sera documentée dans votre dossier médical.

Cette étude a reçu l'avis favorable de la Commission recherche de Terre d'éthique le 30/08/2023

Vous remerciant par avance de la confiance que vous me témoignez, je reste à votre disposition pour tout renseignement complémentaire concernant cette étude.

Flores Rémi

Je soussigné(e) M./M^{me} (Nom, Prénom)
déclare avoir été bien informé(e) sur l'étude « Contraception orale : l'expérience des femmes ». J'accepte de participer à cette étude dans les conditions précisées ci-dessus.

Fait à, en deux exemplaires dont un est remis à l'intéressé(e).

Nom du médecin : Flores	Nom du patient :
Prénom du médecin : Rémi	Prénom du patient :
Date : 19/03/2023	Date :
Signature du médecin :	Signature du patient :



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INTRODUCTION

The lifetime prevalence of all eating disorders (EDs) is 8.4% among women and 2.2% among men¹. EDs include anorexia nervosa (AN), bulimia nervosa (BN), binge eating disorder (BED) and unspecified eating disorders (ED-NS)². ED-NS are present in 60 per cent of individuals seeking help for an ED³ and appear to have the same physical and psychological impact as AN and BN in adulthood^{4,5}. 40 per cent of patients with NS-ED are reported to have a full diagnosis of AN or BN within two years of their first diagnostic consultation³.

Eating disorders are associated with common psychiatric (depression, substance misuse, anxiety) and somatic (malnutrition, oral health problems, digestive disorders) comorbidities. Anorexia nervosa (AN) and bulimia nervosa (BN) are associated with higher rates of suicide⁶⁻⁸, psychiatric comorbidities⁹ and somatic comorbidities¹⁰ compared with unaffected patients. These disorders often begin in adolescence.

Early detection and early therapeutic intervention are thought to improve the prognosis for patients with eating disorders^{2,11-12}.

Primary care is often cited as the setting for the early detection of these disorders¹³, although the effectiveness of screening in primary care has not been proven¹⁴. In the guidelines, general practitioners (GPs) are identified as key players in the detection and management of these patients, particularly as they see adolescents in consultation¹⁵.

Patients with eating disorders consult their GPs more frequently than those without eating disorders in the five years prior to the onset of their disorders¹⁶. However, GPs rarely identify eating disorders¹⁵. GPs were aware of only 50 per cent of their patients with bulimia nervosa (BN)⁽¹⁷⁾. In the same

Crossed glances between patients with eating disorders and GPs: an impossible encounter?

study, no cases of anorexia nervosa (AN) were identified, although GPs at the centre were aware of one such case; however, the patient had refused to respond to the research team¹⁷. The incidence of EDs in primary care is 20 times lower than that reported in studies of the general population¹⁸. The prevalence of eating disorders in primary care ranges from 0 to 1 per cent in British studies¹⁸, with no cases of anorexia identified. There are no French studies on the prevalence of eating disorders in general practice. Nevertheless, the proportion of patients receiving treatment for eating disorders in general practice was 0.3 per cent in French data¹⁴, with a high rate of comorbidity with depression, which is fairly similar to Australian data of a similar nature¹⁹. British qualitative studies have shown that GPs felt involved in supporting patients with EDs, but not in screening for them, and felt a great sense of powerlessness²⁰. No qualitative studies have been carried out in France on this subject.

The objectives of our study were to describe, in a comparative analysis, GPs' perceptions of their care of patients with eating disorders and the perceptions of patients with eating disorders regarding the role of their GP in their care pathway and treatment

METHOD

We conducted a qualitative study using an approach inspired by grounded theory for GPs and patients²¹. The COREQ 32 criteria were used for this study²².

Study population and sampling

This study used data from the General Practice Observatory (OMG) of the French Society of General Practice (SFMG) as its recruitment base, following on from a quantitative study on this subject¹⁴. The initial study population consisted of GPs participating in the OMG data collection. Of these, 62 were still practising at the time of the study. We contacted GPs who had, at least once between 1994 and 2007—the period during which this database existed—recorded an eating disorder as the main reason for consultation in their medical records. If they gave their consent, an interview was conducted. Following the interviews, the GPs were informed that they could recruit one of their patients (male or female) who had been treated for an eating disorder, as recorded in their medical records, so

that their perceptions could be studied in a subsequent phase. These patients had to be over 8 years of age, the age at which eating disorders typically begin according to NICE guidelines.

Data collection

Individual interviews were conducted with GPs and patients, either face-to-face or by telephone, given that this was a national sample. They were carried out by four researchers. An interview guide was used; the GP would describe a situation encountered in their practice and then give their opinion on the role they believed they generally played in the care of patients with eating disorders. For patients, a more flexible interview guide was used to facilitate in-depth and personal discussions.

Data analysis

Data analysis was carried out by three researchers. Triangulation, through discussion and cross-checking, helped to minimise the initial subjectivity of each researcher. For the overall categorisation, a consensus-building process was undertaken using the principle of constant comparison²¹. Coding software (Nvivo10[®]) was used to analyse all these interviews, enabling matrix coding, which involved selecting the most explanatory categories and cross-referencing them to identify the ideas underpinning the mirror model. The mirroring of the explanatory model involved comparing the categories derived from the two studies to reconstruct the social interactions between GPs and patients. Interviews were

conducted until data saturation was reached²¹

Deconstructing preconceptions and the field diary

We compiled a logbook that reflected our perceptions, which gradually evolved as we engaged with the fieldwork, and which enabled us to adjust the questions in the interview guide. In our view, the GP had a role to play in coordinating the various specialists (nutritionists, psychologists, psychiatrists) and in monitoring weight, and maintained a relationship of trust with these patients. We realised that we had adopted a hospital-centred approach, that is to say, a perception that the responsibilities of healthcare professionals were divided according to their specialism. We expected patients to recount difficult life stories linked to their family circumstances. We also anticipated a lengthy and difficult recruitment process.

Ethics Committee

All study participants gave their verbal consent. The study received approval from the Centre Ouest 1 Human Research Ethics Committee (CPP 2013-N10).

METHOD

24 GPs and 6 female patients were interviewed between 2014 and 2016; all GPs and 5 female patients were interviewed face-to-face, whilst one female patient was interviewed by telephone at her request (sessions lasting between 19 minutes and 1 hour 19 minutes). (Tables 1 and 2).

Four mirror-image categories have emerged.

Eating disorders: a situation rarely encountered by GPs, despite patients' long-standing family and personal problems

GPs found it difficult to define eating disorders because they are rarely encountered: "Well, er... it's a bit complicated to define... so actually..." (GP4A) "I was actually looking into it just before you arrived; it's something that's very rare. There are years when we don't see any at all. I think over the last four years I've only come across it two or three times at most." (GP2B). They were able to identify a certain unease but struggled to distinguish between a normal and a pathological situation: "People who are concerned about their body image, who, er... are... well, ultimately I think these people have eating behaviour that's, er.....normal, shall we say—if we can use that word—and who are constantly plagued by guilt about what they eat, telling themselves, 'I'm going to have this, it'll make me put on weight,' well..." (MG5B).

The patients said they had always lived with a psychiatric disorder – often initially that of their parents – and a sense of shame, sometimes from childhood onwards during episodes of compulsive eating, having learnt to conceal the disorder: "She was already depressed; I lived through it. I really have memories from when I was little of my mother

	General practitioner (GP): n=24
Age	56.5 years (45–63)
Gender	
Male	22 (91.6%)
Female	2 (8.4 per cent)
Occupation	
Rural	7 (29.1%)
Semi-rural	3 (12.6 per cent)
Urban	14 (58.3%)
Type of practice	
Alone	6 (25 per cent)
In a group	18 (75%)
Region	
Île-de-France	7 (29.2%)
Burgundy-Franche-Comté	4 (16.6%)
Nouvelle-Aquitaine	3 (12.5%)
Centre-Val de Loire	3 (12.5%)
Auvergne-Rhône-Alpes	2 (8.3%)
Grand Est	2 (8.3%)
Brittany	1 (4.2%)
Normandy	1 (4.2%)
Hauts-de-France	1 (4.2%)
Installation	
Less than 10 years	0
10 to 20 years	5 (20.9%)
Over 20 years	19 (79.1%)
Further training	
Hypnosis	2 (8.3%)
Psychotherapy	5 (20.9%)
None	17 (70.8%)

Table 1 - Characteristics of the GPs interviewed



	Gender	Age (years)	Occupation	Marital status	Eating disorder	Reported comorbidities	History of hospitalisation for eating disorders	Duration of consultations (min)	Age at diagnosis (duration of follow-up with the GP since first contact)
P1	Female	44	Looking for work	Divorced twice, no children	Anorexia Mental health condition with binge-eating episodes and vomiting, as reported by the patient	Depression	Yes	79	25 years old (19 years old)
P2	Female	21	Economics student	Single No children	Subsyndromic form of anorexia diagnosed by the GP	Depression	No	45	20 years (5 years)
P3	Female	24	Business school student	Single No children	Anorexia Restrictive-type mental disorder as reported by the patient	Not described	No	31	18 years (7 years)
P4	Female	57	On disability benefit, primary school teacher	In a relationship No children	Binge eating Bulimia, as reported by the patient	Depression	Yes	19	30 years old (35 years old)
P5	Female	51	Accounting manager	Divorced, 3 children	Subsyndromic form of bulimia diagnosed by GP	Thyroid cancer	No	54	35 years (23 years)
P6	Female	41	Account manager	In a relationship, separated from the father of her two children	Anorexia nervosa with binge-eating episodes and vomiting, as reported by the patient	Depression Alcohol dependence Sleep disorder	No	55	32 years old (6 years)

Table 2 - Characteristics of the patients interviewed

being depressed and suicidal. These are things that are still, truly, painful" (P6) "I was waiting for just one thing: for my parents to leave the house, which happens... which doesn't happen all that often, and there you go—all it took was a bit of fresh bread in the house, and I'd rush to the fridge to spread a huge layer of butter on it. I was well aware that it wasn't normal." (P4), and a need for comfort shared by all

The encounter between the GP and the patient with an eating disorder: the clash between the two parties and the relief of revealing the disorder

The patients had all experienced the diagnosis from their GP as a shock followed by relief and hope of recovery: *"It's hard to hear when they tell you that. I mean, deep down we know it, but... Ah, it feels strange; you think to yourself: getting past the denial during the consultation" (P6)* The GPs were suddenly made aware of the physical, verbal and sexual abuse experienced by the patients *"So, er... and that's when it started; I think it was from her that I began to make the connection, er... between eating disorders and incest. And to systematically ask the question afterwards." (GP6B) "Because there are psychological disorders that stem from childhood, involving abuse by both the mother and the father." (GP4C)* on the difficulty of providing care and the family environment;

Managing eating disorders on a day-to-day basis: patients' isolation and shame, and GPs' initial sense of helplessness

Some female patients spoke of social isolation, sometimes complete: *"I had to stop working, even though I had a job." (P4) "No, we hide away, basically. We... we distance ourselves from people, because we have to..." (P6), accompanied by a sense of shame about discussing eating disorders and a secret buried within everyday life: "My partner had to break the lock. And then, for me, when I saw that, it was terrible; I thought to myself: this is going to be a disaster, I won't be able to lock myself away anymore." (P5). The GPs, for their part, expressed a sense of incompetence and initial helplessness when faced with patients' everyday situations: *"... and for those with bulimia, protecting yourself, because you can be taken in" (MG6B) "you're not necessarily well equipped. So I'd say the first feeling I'd mention is a sense of unease. Er... probably a sense of, er... limited competence, I'd say." (MG2B).* The GPs focused on treating the associated depression: *"ultimately, it's the depression that I'll tackle first" (MG5C).**

A fundamental therapeutic alliance: the GP as a trusted figure, but the risk of emotional depen-

dence

The GPs wanted to establish a climate of trust from the outset without becoming too involved: *'Well, I try to make sure she suffers as little as possible' (GP5B), 'the role was to, er... it was to have established a climate of trust so that she could open up, but without being too intrusive' (MG7C)*. They emphasised the importance of a good care network to avoid the all-too-common feeling of professional isolation: *"There's a coordinating role, isn't there? To put people in touch and maintain the connection, to maintain the relationship... the relationship with the patient and to work on that and to keep having an influence, to keep monitoring, objectives, well, things like that. But to, you know, give a bit of guidance and organise things."* (MG10C) *"The problem, as in practically all psychiatric care, is that we don't get any feedback."* (MG5C). Patients regularly expressed a very strong emotional bond with their GP and a fear of not being heard, or even of being abandoned: *"It's a relationship of trust. I'd even say that... it goes beyond the medical relationship."* (P4) *'What I'm saying is pessimistic, but, er, I think it's going to become increasingly rare to be listened to' (P5). 'I was, er, with schizophrenics; I wasn't with people, er, they put me in with them – that's how they do it in hospital' (P1)*

DISCUSSION

An impossible encounter between GPs and patients with eating disorders

A difficult, even impossible, encounter arose between GPs, who felt powerless and incompetent, and patients, who felt ashamed and isolated. The results showed that GPs and patients struggled to interact during these care encounters.

GPs' sense of incompetence and the search for solutions

GPs described these care pathways as difficult and time-consuming. They expressed a sense of helplessness, or even uselessness, as reported in the literature^{20,23}. Whilst some GPs in our study reported difficulties in accessing specialist services, as noted in the literature²³, others had resorted to a multidisciplinary approach, which helped to alleviate their sense of difficulty or incompetence, as described previously²⁴.

In a study from the English-speaking world, 59 per cent of GPs did not believe they had the necessary skills to diagnose and subsequently manage patients with eating disorders²⁵. As for psychiatrists, in another study, they were more comfortable with diagnosis than with patient management²⁶.

From denial to realisation: confidence as the solution

Our study identified feelings of shame and denial as major barriers to seeking care amongst patients. These barriers are well documented in the literature, as are a lack of awareness of therapeutic resources and support networks, negative attitudes amongst

healthcare professionals, and a lack of encouragement from those close to the patient²⁷.

The eating disorder was described by patients as an unexpected event that had 'come out of the blue'. It was sometimes described as a 'thing', which Laplantine characterised as an external enemy²⁸. This notion of an external enemy was an expression of denial. The surprise at the existence of the condition likely reflected the strong denial associated with the eating disorder. Some patients reported difficulties in accessing care (suitable facilities, specialised adult inpatient units), in line with a UK study describing inadequate development of the care network and funding-related barriers to access²⁹.

In our sample, the women reported having experienced psychiatric symptoms prior to the onset of the eating disorder. One had suffered from anxiety disorders. Several described depression, with severe manifestations such as self-harm and suicide attempts – comorbidities documented in the literature¹⁰.

The patients described their GP as a trusted figure in their care pathway. In a study of patients with eating disorders, feelings of support and satisfaction with care were higher when the GP was available, particularly in relation to the eating disorder³⁰.

Strengths and weaknesses of the study

To our knowledge, this was the only French qualitative study on the subject, despite the data having been collected some time ago.

Our national sample ensured that diversity was taken into account. Nevertheless, all GPs were members of the SFMG. Patient recruitment proved difficult. Over a 12-month period, the contact details of only 8 women were provided by 3 GPs from different practices and with different profiles who had nothing in common. According to the GPs, no men were affected by the issue, even though there were a few in the SFMG cohort studied; this may be linked to the predominantly female perceptions of eating disorders in our Western society²³. We were therefore only able to interview women on this subject. One woman declined and another died before the interview could take place. The duration of the interviews was shortened for some patients due to their state of health. Data saturation was probably not achieved. The mirroring approach highlighted just how difficult the encounter between GPs and patients with eating disorders can be.

Telephone interviews were chosen for practical reasons, despite the lack of body language and a likely reduction in the level of trust. Telephone interviews are recognised as being equivalent to face-to-face interviews³¹.

Outlook

Encounters between patients with eating disorders and GPs are made difficult by factors internal to both patients and doctors, but also by a lack of structure in the care pathway. Working within a relationship based on the therapeutic alliance enables

GPs to make a diagnosis and help patients, thereby enabling them to move beyond denial³².

Towards a biopsychosocial approach to eating disorders in primary care?

GPs appeared to frame eating disorders within a holistic, biopsychosocial approach by supporting patients in their social and family circumstances, whilst incorporating the management of symptoms of depression. GPs have a general competence in managing the burden of illness, that is, the impact of a chronic condition on overall quality of life. This competence is not specific to eating disorders, and GPs should approach the management of these disorders in the same way as common chronic conditions in the MS population (diabetes, cancer), with the same facilitating factors and the same barriers³³.

Exploring self-esteem

Studies have shown a link between low self-esteem and the onset of EDs³⁴. A marked sense of shame about one's own body during adolescence was an early predictor of the onset of these disorders in adulthood, a finding also observed in our study. Studies could be conducted in cohorts of adolescents attending clinics for chronic conditions to explore the significance of low self-esteem in the onset of eating disorders.

Addressing doctors' negative perceptions

A recent qualitative study explored how GPs' negative perceptions of patients with eating disorders began as early as medical school³⁵. More specific training in empathy, involving discussion groups modelled on the Balint method, for example, would help healthcare professionals develop a reflective approach towards patients with chronic conditions characterised by a poor prognosis and denial. The aim of these groups is to simulate situations that healthcare providers find difficult, so that they can learn to ma-

nage them effectively in the future³⁶.

A multi-professional care network facilitating contact between GPs and patients with eating disorders

The lack of a clear pathway in the care process is an obstacle to identifying these situations. Once such a pathway is established and well-known, the rate of identification increases³⁷. In France, some existing networks rely on tertiary care services specifically for eating disorders, accessible to patients via a voluntary organisation such as the French Federation for Anorexia and Bulimia (FFAB), which offers a dedicated helpline and involves patient partners. GPs have a vital role to play in structuring this care pathway, both physically and psychologically.

CONCLUSION

Our qualitative study highlighted the major challenges faced by GPs and patients with eating disorders, characterised by a sense of helplessness among healthcare providers and persistent shame among patients. The results underscored the gap between the perception of eating disorders as a rare condition in primary care and their complex reality, often linked to early-life trauma and psychiatric comorbidities. The therapeutic alliance was hampered by the absence of structured care pathways and a lack of specific training. An integrated biopsychosocial approach, combining capacity-building for GPs, multidisciplinary coordination and awareness-raising, appears essential to improve screening and support.

The authors have declared that they have no conflict of interest regarding the data published in this article. The declarations of interest for each of the article's authors are available online at www.transparence.gouv.fr.

Abstract

Introduction. Eating disorders, which are common in the general population, are associated with severe psychiatric and physical comorbidities. Early detection of EDs would improve the prognosis for patients with EDs. General practitioners (GPs) are often cited as the key players in the early detection of EDs, whilst the patients concerned do not seem to discuss this during consultations. There is little data to explain this discrepancy.

Objective. To compare GPs' perceptions of their care for patients with EDs with those of patients with EDs regarding the role of their GP in their care pathway and treatment.

Methods. A qualitative study using a grounded theory approach. GPs participating in the General Practice Observatory's database were recruited; they in turn recruited patients with eating disorders whom they were treating in their practices. Individual interviews were conducted, and a constant comparative analysis contrasting GP and patient perspectives, with triangulation by three researchers, was carried out.

Results. 24 GPs and 6 female patients were interviewed. The four categories identified were: 1) Eating disorders: a condition rarely encountered by GPs, despite the patients' long-standing family and personal problems; 2) The encounter between the GP and the patient with an eating disorder: the clash between the two parties and the relief brought by the disclosure of the disorder; 3) Managing the eating disorder on a day-to-day basis: the patients' isolation and shame, and the GPs' initial sense of helplessness; 4) A fundamental therapeutic alliance: the GP as a trusted figure, but with the risk of emotional dependence.

Discussion. An impasse was observed between GPs feeling helpless and incompetent and patients experiencing shame and isolation. GPs appeared to adopt a biopsychosocial approach to patients with eating disorders, were able to draw on specific networks within tertiary care, and needed to address their own negative perceptions. It seems important to remind GPs of the need to identify low self-esteem in adolescents as a marker for eating disorders, and to utilise emotion-focused practice groups.

Keywords: Eating disorders – primary care – qualitative research.

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Efficacy of topical NSAIDs in tendinopathies

Systematic review of randomised controlled trials

INTRODUCTION

Tendinopathies are common musculoskeletal disorders, accounting for 12.6% of general practice consultations in France¹. Tendinopathies are defined as persistent tendon pain and loss of function related to mechanical loading, with damage to tendons and adjacent structures such as tendon sheaths and bursae.

Non-steroidal anti-inflammatory drugs (NSAIDs) are widely prescribed for musculoskeletal disorders². In France, in 2022, 43 million packs of oral NSAIDs and 22.5 million packs of topical NSAIDs were reimbursed by the National Health Insurance Scheme, at a cost of 74 million euros³. Some are also available over the counter. Systemic NSAIDs, however, are associated with numerous drug interactions and adverse effects^{4,5}. Consequently, topical NSAIDs appear to be a promising alternative. Safety analyses of topical NSAIDs show no more systemic adverse effects than placebo and in particular no gastrointestinal disturbances. The adverse effects observed are mild and transient local skin reactions, except for ketoprofen, which carries a risk of severe photoallergic skin reactions⁶. Several meta-analyses have been carried out to assess their efficacy. The Topical NSAIDs appear to provide relief for certain acute and chronic musculoskeletal conditions: this is the case for various topical formulations of diclofenac and ketoprofen, which have shown superior results to placebo in providing at least 50 per cent relief from pain associated with sprains and strains after seven days of treatment⁷. In lateral elbow tendinopathy efficacy is inconclusive due to low quality and conflicting evidence⁸. The efficacy of topical NSAIDs on other tendinopathies has not been the subject of a literature review to date.

The aim of this study was to evaluate the efficacy of topical NSAIDs in tendinopathy management.

METHOD

A systematic review of the literature on randomised controlled trials (RCTs) was conducted.

Protocol and Registration

The protocol for this review was registered on January 5, 2023, on the PROSPERO platform under registration number CRD42023389622. Amendments were made to the protocol. The initial five compounds did not include indomethacin, which was added. When an outcome measure concerning the reduction of pain was measured on several occasions, the measurement taken on the latest day was selected, as it was deemed the most clinically relevant.

This systematic review follows the PRISMA⁹ guidelines.

The risk of bias in the RCTs was assessed using version 2 of the *Risk of Bias Tool* (RoB2)¹⁰ in accordance with the *Rebuild the Evidence Base* (REB)¹¹ methodology.

Eligibility criteria

The eligibility criteria for studies included in this systematic review were as follows:

- randomised clinical trials;
- comparison of topical NSAIDs versus placebo;
- evaluation of the efficacy of NSAIDs in treating pain associated with acute or chronic tendinopathies of the upper or lower limbs;
- publication in English, French or Italian.

There were no restrictions on dosage, duration of treatment or the year the study was published.

The condition under investigation was tendinopathy, including associated bursitis, regardless of its location (upper or lower limbs). Other musculoskeletal disorders, including sprains, flare-ups of osteoarthritis and low back pain, were excluded.

Search methods

The search for eligible trials was conducted in the main open-access medical bibliographic databases: Medline (PubMed®), the Cochrane Central Register of Controlled Trials (CENTRAL®) and Clinical-Trials.gov.

Trials not found in these databases but included in the meta-analyses of the systematic review and meeting the eligibility criteria were included. The literature search was conducted until 30 April 2023. The search query was based on the following MeSH terms: (((diclofenac[MeSH Terms]) OR (diclofenac*)) OR ((piroxicam*) OR (piroxicam[MeSH Terms])) OR ((indomethacin[MeSH Terms]) OR (indomethacin*)) OR ((niflumic acid*) OR (niflumic acid[MeSH Terms])) OR ((ketoprofen) OR (ketoprofen[MeSH Terms])) AND ((administration, topical[MeSH Terms]) OR (topic*)) AND ((tend*) OR (tendinopathy [MeSH Terms])) AND (randomised controlled trial*[all fields])).

An initial search was carried out for all studies examining the efficacy of topical NSAIDs in tendinopathies. This initial search identified six active substances: diclofenac, diclofenac epolamine, ketoprofen, niflumic acid, piroxicam and indomethacin. No RCTs comparing topical ibuprofen with placebo could be identified.

Two researchers (CI and CB) reviewed the titles and abstracts of the studies to identify those that might be eligible. To confirm eligibility, the articles were read in full and analysed by the same researchers. In the event of disagreement, a third researcher (RB) was consulted.

Two researchers (CI and CB) independently extracted the characteristics of each trial (Appendix 1).

Risk of bias

The methodological quality of the various trials was assessed using the RoB2 tool by two researchers (CI and CB). A third researcher (RB) was consulted in the event of disagreement. Five areas of bias were analysed, with each assigned a risk classification (low risk, high risk, uncertain risk). Only trials with a low risk of bias were analysed (Tables 1 and 2 on the following page).

Multiple statistical tests

For trials with multiple outcome measures, methods for controlling for multiple statistical tests to mitigate the inflation of the overall alpha risk were sought (hierarchical sequential analysis, the Bonferroni method, etc.). Where no adjustment method was available, the trial results were considered 'exploratory' rather than 'confirmatory', due to a high risk of false positives due to the large number of statistical tests¹².

Quantification and synthesis of results

The primary outcome measure (POM) was the improvement in pain on movement between the third and sixth day, measured on a continuous scale (pain score).

A qualitative analysis was carried out on all the included trials to determine whether their results were confirmatory or exploratory in nature. This analysis aimed to identify, for each trial, the nature of the scientific approach adopted by the authors, distinguishing between confirmatory and exploratory approaches.

Risk of cross-sectional bias and assessment of the level of evidence

The level of evidence was assessed using the four-level REB framework: firm evidence, evidence requiring confirmation, a signal requiring confirmation, or absence of evidence. This framework incorporates the confirmatory nature of systematic reviews and RCTs with a low overall risk of bias, statistical heterogeneity across RCT results, and the risk of publication bias assessed using funnel plots and trial registry analyses. An outcome measure is considered 'confirmatory' if it achieved statistical significance for the prespecified criteria defined in the study protocol and statistical analysis plan, while accounting for multiplicity and Type I error. Otherwise, it is considered 'exploratory', generating a hypothesis requiring confirmation in a future RCT.

RESULTS

Selection of trials

The PRISMA trial selection flowchart is shown in figure. A literature search of the three databases identified 394 trials. No further trials were found via other sources, including existing meta-analyses.

Three hundred and eighty-one articles were excluded. An assessment of the bias risk in the remaining 13 trials (Tables 1 and 2) led to the selection of 4 trials with a low risk of bias^{6,13,24}.

Characteristics of the Selected Trials

The summary, characteristics and results of each of the four RCTs are presented in Table 3.

All trials evaluated a topical NSAID versus placebo.

Essay	D1	D2	D3	D4	D5	Total
E. Bussin, et al. 2021 ²¹	+	+	!	+	+	+
M. Galeazzi, et al. 1993 ⁷	+	+	+	+	+	+
A. Russel, 1991 ¹⁸	+	+	+	+	+	+
G. Spacca, et al. 2005 ¹³	+	+	+	+	+	+
J. May, et al. 2007 ¹⁵	+	+	!	+	+	+
B. Mazière, et al. 2005 ²²	+	+	+	+	+	+
R. Dreiser, et al. 1991 ⁶	+	+	+	+	+	+
J. Audair, et al. 1989 ⁸	!	!	!	+	+	!
L. Chen, et al. 2006 ¹⁶	!	!	!	+	!	!
P. Jenoure, et al. 1997 ¹⁷	+	+	+	+	+	+

Table 1 - Risk of bias in parallel-group trials according to RoB2

D1: randomization process; D2: deviation from the intended intervention; D3: missing data; D4: outcome measurement; D5: selection of reported outcomes; +: low risk; !: uncertain risk; -: high risk.

Essais	D1	D5	D2	D3	D4	D5	Total
R. Burnham, et al. 1998 ²⁰	+	+	-	-	+	-	-
E. Bussin, et al. 2017 ¹⁹	+	+	+	+	+	+	+
F. Ginsberg, et al. 1991 ¹⁴	+	-	+	+	+	-	-

Table 2 - Risk of bias in crossover trials according to RoB2
D1: randomization process; SD: standard deviation; D2: difference from the intended intervention ; D3: missing data; D4: outcome measurement; D5: selection of reported outcomes; +: low risk; -: high risk.

bo. Three trials were multicentre, parallel-group studies; the fourth was a single-centre, crossover trial^{6,13,19,22}. Each RCT evaluated a different active substance: diclofenac, diclofenac epolamine, ketoprofen and niflumic acid^{6,13,19,22}. The duration of treatment ranged from three to fourteen days.

Analysis of RCTs

The outcome measure for pain on movement, as assessed by the EVA, was supportive in each of the 4 RCTs (**Appendix 2**).

RCTs with a low risk of bias on diclofenac epolamine, ketoprofen and niflumic acid were conclusive regarding the reduction of pain on movement in acute tendinopathies: diclofenac epolamine was evaluated in shoulder and elbow tendinopathies ; ketoprofen for tendinopathies of the shoulder, elbow, knee, and ankle; finally, niflumic acid was evaluated for tendinopathies of the upper and lower extremities (supraspinatus, biceps brachii long, epicondyle, epitrochlea, thumb, lower extremity extensors, Achilles tendon)^{6,13,22}. The results of these RCTs were as follows: for diclofenac epolamine, the standardized mean difference (SMD) was -0.49 with a 95% CI of -0.81 to -0.17 and $p < 0.001$; for ketoprofen, SMD = -0.51 with 95% CI = -0.81 to -0.2 and $p = 0.013$; for niflumic acid, SMD = -0.82 with 95% CI = -1.37 to -0.27 and $p = 0.004$.

This was not the case for the low-risk-of-bias RCT on diclofenac, where only the secondary endpoint "Overall improvement as assessed by the patient" was statistically significant in the treatment group compared to the placebo group. This was therefore considered an exploratory endpoint.¹⁹

Assessment using the REB method

No RCTs with a low risk of bias were identified for piroxicam, indomethacin and ibuprofen. There is publication bias due to the presence on ClinicalTrials.gov of a study protocol evaluating the efficacy of topical diclofenac in tendinopathies, as well as two study protocols evaluating ketoprofen, the results of which have not been published²³⁻²⁵. For diclofenac epolamine and niflumic acid, the REB method assessment concludes that there is '*conclusive evidence to be confirmed*'. This indicates promising results, which must be confirmed by a RCT to demonstrate 'strong evidence'. For ketoprofen, the REB assessment concludes that there is a '*signal to be con-*

firmed'. In contrast, for diclofenac alone, indomethacin, piroxicam and ibuprofen, the assessment concludes that there is a lack of evidence (**Appendix 3**).

DISCUSSION

Summary and interpretation of the results

According to the REB methodology, topical diclofenac epolamine, ketoprofen and niflumic acid appear to be effective in certain acute tendinopathies of the upper and lower limbs for reducing pain on movement, with a level of evidence according to REB classified as 'conclusive result to be confirmed' for diclofenac epolamine and niflumic acid, and 'signal to be confirmed' for ketoprofen. There is no evidence for diclofenac alone, indomethacin, piroxicam or ibuprofen.

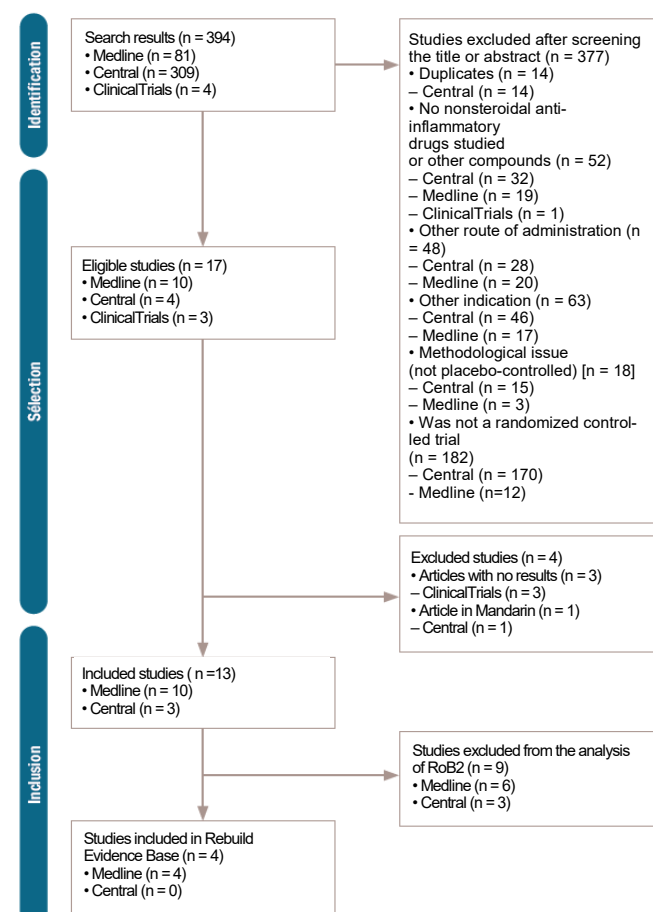


Figure - Study Selection Flowchart

Adapted from: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ* 2021;372:n71. doi: 10.1136/bmj.n71. For more information: <http://www.prisma-statement.org/>

	Pain assessment					
	Outcome measure	Nature of the criterion	NSAIDS	PBO	Results	
E. Bussin et al. 201719	Pain on movment	Confirmatory criteion	DM = 3.1 (DS=3.1)		DMS: -0.20 95% CI = -0.79–0.39	<i>p</i> -value not available, not significant
	Pain at rest	Exploratory criterion	DM = 2.3 (SD = 1.5)	MD = 2.7 (SD = 2.03)	DMS = -0.22 95% CI = -0.81 to -0.37	<i>p</i> -value not available, not significant
	Pressure pain threshold		MD = -270 (SD = 190)	MD = -280 (SD = 170)	MSD = 0.05 95% CI = -0.54 to -0.65	<i>p</i> -value not available, not significant
	Overall improvement as assessed by the patient		55 per cent	23%	RR = 2.40 95% CI = 1.02–5.67	<i>p</i> = 0.041
G Spacca, et al. 200513	Pain on movement at day 3	Confirmatory criterion	DM = 53.2 (SD = 21.4)	DM = 63 (SD = 18.6)	SMD = -0.49 95% CI = -0.81 to -0.17	<i>p</i> < 0.001 values from the table (values in the text are slightly different)
	Pain on movement at day 6		MD = 40 (SD = 23.6)	DM = 51.7 (SD = 19.6)	DMS = -0.54 95% CI = -0.86 to -0.22	<i>p</i> < 0.001 values from the table (values in the text differ slightly)
B. Mazieres, et al. 200522	Pain during daily activities at day 7	Confirmatory criterion	DM = 30.8 (SD = 23.8)	MD = 44.3 (SD = 25.6)	DMS = -0.51 95% CI = -0.81 to -0.2	<i>p</i> = 0.0013
	Pain at rest on day 7	Exploratory criterion	MD = 21 (SD = 21)	DM = 33 (SD = 26)	DMS = -0.51 95% CI = -0.81 to -0.20	<i>p</i> = 0.0005
	Pain on palpation at day 7		DM = 1.2 (SD = 0.9)	DM = 1.5 (SD = 0.9)	DMS = -0.33 95% CI = -0.63 to -0.03	<i>p</i> = 0.0429
	Overall improvement as assessed by the patient		57.5%	48.2%	RR = 1.19 95% CI = 0.90–1.58	<i>p</i> -value not available, not significant
	Overall efficacy assessed by the examiner		69%	53%	RR = 1.30 95% CI = 1.02–1.66	<i>p</i> -value not available
R. Dreiser, et al. 19916	Pain on movement	Confirmatory criterion	DM = 23.64 (DS = 16.99)	DM = 42.67 (SD = 27.77)	DMS = -0.82 95% CI = -1.37 to -0.27	<i>p</i> = 0.004
	Improvement in pain at rest	Exploratory outcome	88.2%	70.6%	No results available (discrete outcome measure not eligible for inclusion in the meta-analysis)	<i>p</i> < 0.01
	Improvement in tenderness on palpation		86.2%	51.8	No results available (discrete criterion, therefore not eligible for inclusion in the meta-analysis)	<i>p</i> < 0.01
	Overall improvement as assessed by the patient		85.8%	53.9%	RR = 1.60 95% CI = 1.07–2.38	<i>p</i> < 0.05
	Overall improvement as assessed by the examiner		86.2%	40.7%	RR = 2.12 95% CI = 1.31–3.41	<i>p</i> < 0.01

Table 3 – Summary of results from the included trials

95% CI: 95% confidence interval; D: day; MD: mean difference; SD: standard deviation; SMD: standardised mean difference; RR: relative risk.

Limitations

The first limitation of this review concerns the heterogeneity of the trial characteristics. The duration and location of the tendinopathies varied considerably, and they were either acute or chronic depending on the trial. Treatment durations also varied, ranging from three to fourteen days.

The second limitation is potential publication bias that may affect the level of evidence. Three studies evaluating ketoprofen and diclofenac in tendinopathies, conducted by pharmaceutical companies, are registered on ClinicalTrials.gov, but their results have not been published and therefore could not be included in this review. Unpublished data may indicate inconclusive results, which therefore calls for caution in interpreting the results²³⁻²⁵.

The primary outcome measure was the pain experienced by the patient, which is a subjective outcome measure, in the absence of a standardised objective measure. Analysing the functional impact of pain is complex due to its subjective and multidimensional nature, which involves physical abilities, daily activities and quality of life. The variety of tools available to assess pain and the changing nature of symptoms also limit the comparability and standardisation of results.

Comparison with the literature

These results are consistent with a meta-analysis on the subject, published by Pattanittum *et al.* in 2013, which supports the efficacy of topical diclofenac in relieving pain associated with epicondylar tendinopathies²⁶. In its assessments, the Transparency Commission considered the clinical benefit of diclofenac and niflumic acid to be moderate for the indication 'symptomatic treatment of superficial tendinitis' when applied topically^{27,28}. The results concerning diclofenac alone are at odds with the Transparency Commission's assessment of diclofenac. This discrepancy could be explained by the fact that, in this study, diclofenac alone and diclofenac epolamine were analysed separately.

Regarding ketoprofen, the conclusions of this review in favour of its efficacy, are at odds with a medical benefit deemed 'insufficient' due to an identified risk of a serious photoallergic cutaneous adverse reaction^{29,30}.

Implications for clinical practice

Two compounds, diclofenac epolamine and niflumic acid, appear to be the preferred options in clinical practice, based on these results. However, the systemic bioavailability of these two substances varies

significantly: niflumic acid has a plasma bioavailability of 20 per cent (compared with only 5 per cent for diclofenac epolamine), which implies greater absorption into the systemic circulation and therefore carries a higher risk of adverse effects, particularly gastrointestinal³¹.

Diclofenac epolamine could therefore be recommended as first-line treatment, due to lower bioavailability and a more favourable safety profile, particularly in terms of systemic effects. However, it has only been evaluated in certain types of tendinopathy, and its generalised use for all tendinopathies is therefore questionable.

Regarding ketoprofen, the level of evidence for its efficacy remains lower than that for the two drugs mentioned above. It carries an increased risk of causing photoallergic skin reactions (particularly following exposure to sunlight or UV rays)³². It is therefore necessary to weigh up the benefits and risks of its use, before its recommendation in clinical practice.

Indomethacin and piroxicam are no longer available in topical form, which excludes them from the current therapeutic arsenal. Similarly, ibuprofen and diclofenac, when used alone in topical form, cannot be considered as treatment options due to the lack of robust data from RCTs on their efficacy in this context. These compounds cannot therefore be recommended in clinical practice.

Finally, it is legitimate to discuss with the patient the option of withholding treatment for these conditions, depending on the intensity of the pain experienced and the impact on daily functioning.

Implications for research

Given the small number of RCTs eligible for assessment using the REB method, further high-quality, low-risk RCTs are needed to strengthen the evidence for the analgesic efficacy of topical NSAIDs in tendinopathies, which are widely used in clinical practice. Such studies should confirm the efficacy of diclofenac epolamine and niflumic acid and evaluate topical formulations of ibuprofen and diclofenac, for which evidence remains limited.

Declarations of interest:

The authors have declared that they have no conflicts of interest regarding the data published in this article. The conflicts of interest for each of the article's authors are available online at www.transparence.sante.gouv.fr

Abstract

Background. Tendinopathies are a type of musculoskeletal disorder, accounting for 12.6% of general practice consultations in France. Non-steroidal anti-inflammatory drugs (NSAIDs) are widely prescribed for this condition. Several meta-analyses concerning their topical forms have been conducted, supporting their efficacy in relieving certain musculoskeletal disorders, albeit with low levels of evidence quality.

Objective. To assess the efficacy of topical NSAIDs in the management of tendinopathies.

Methods. A systematic review of the literature was carried out by searching the main medical literature databases. Only randomised trials evaluating a topical NSAID against placebo in the treatment of tendinopathies were included. Their risk of bias was assessed using the RoB2 (risk of bias 2) method. The outcome measure assessed was improvement in pain on movement. The level of evidence from the RCTs (randomised controlled trials) was assessed using the REB (*Rebuild the evidence base*) method.

Results. Four trials with a low risk of bias were included, covering four active substances. The trials on diclofenac epolamine, ketoprofen and niflumic acid were conclusive regarding the reduction of pain on movement. The trial on diclofenac alone was inconclusive regarding this outcome measure. The assessment of efficacy using the REB method concluded that there was 'convincing evidence to be confirmed' for diclofenac epolamine and niflumic acid, and a 'signal' to be confirmed for ketoprofen. It concluded that there was a lack of evidence for diclofenac alone, indomethacin, piroxicam and ibuprofen.

Conclusion. Of all the topical NSAIDs available, only diclofenac epolamine and niflumic acid have established efficacy, with a sufficient level of evidence. These results should be confirmed by a second randomised clinical trial with a low risk of bias.

Keywords: diclofenac; ketoprofen; niflumic acid; topical administration; tendinopathy; randomised controlled trial.

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APPENDIX II - TEST RoB

E. Bussin, <i>et al</i> 2017			
Domain	Signalling question	Response	Comments
Bias arising from the randomization process	1.1 Was the allocation sequence random?	Y	Randomization and blinding were adhered to.
	1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	Y	
	1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	NI	No analysis of characteristics in the two groups.
	Risk of bias judgement	Low	
Domain S: Risk of bias arising from period and carryover effects	S.1 Was the number of participants allocated to each of the two sequences equal or nearly equal?	N	12 vs. 7 = 63% vs. 37%
	S.2 If N/PN/NI to S.1: Were period effects accounted for in the analysis?	Y	No period effect
	S.3 Was there sufficient time for any carryover effects to have disappeared before outcome assessment in the second period?	PY	A 1-week washout period is acceptable because the half-life of diclofenac is 10%, which equals 2 days
	Risk of bias judgement	Low	
Bias due to deviations from intended interventions	2.1 Were participants aware of their assigned intervention during the trial?	N	Triple-blind. Similar tubes.
	2.2 Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?	N	
	2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the experimental context?	NA	
	2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?	NA	
	2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?	NA	
	2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	Y	All randomized patients were included in the analysis, with no deviations from the protocol.
	2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?	NA	
	Risk of bias judgement	Low	
Bias due to missing outcome data	3.1 Were data for this outcome available for all, or nearly all, participants randomized?	Y	
	3.2 If N/PN/NI to 3.1: Is there evidence that result was not biased by missing outcome data?	NA	
	3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?	NA	
	3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?	NA	
	Risk of bias judgement	Low	
Bias in measurement of the outcome	4.1 Was the method of measuring the outcome inappropriate?	N	EVA au hopping test.
	4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	N	
	4.3 Were outcome assessors aware of the intervention received by study participants?	N	Blindness was respected; no EI was reported in any of the groups.
	4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	NA	
	4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?	NA	
	Risk of bias judgement	Low	
Bias in selection of the reported result	5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	Y	Protocol published.
	5.2 ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	N	Only one primary evaluation criterion
	5.3 ... multiple eligible analyses of the data?	N	
	5.4 Is a result based on data from both periods sought, but unavailable on the basis of carryover having been identified?	N	Measurements were indeed taken during both treatment periods (PBO and diclofenac).
	Risk of bias judgement	Low	
Overall bias	Risk of bias judgement	Low	

G. Spacca, *et al.* 2005

Domain	Signalling question	Response	Comments
Bias arising from the randomization process	1.1 Was the allocation sequence random?	NI	"randomization"
	1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	PY	
	1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	N	Analysis of comparable characteristics in the two groups.
	Risk of bias judgement	Low	
Bias due to deviations from intended interventions	2.1. Were participants aware of their assigned intervention during the trial?	PN	Blind.
	2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?	PN	
	2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the experimental context?	NA	
	2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?	NA	
	2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?	NA	
	2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	Y	ITT.
	2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?	NA	
	Risk of bias judgement	Low	
Bias due to missing outcome data	3.1 Were data for this outcome available for all, or nearly all, participants randomized?	PY	158 patients were included, and 155 were analyzed = 2% missing data.
	3.2 If N/PN/NI to 3.1: Is there evidence that result was not biased by missing outcome data?	NA	
	3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?	NA	
	3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?	NA	
	Risk of bias judgement	Low	
Bias in measurement of the outcome	4.1 Was the method of measuring the outcome inappropriate?	N	EVA on Day 3 and Day 6 for the most painful movements.
	4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	N	
	4.3 Were outcome assessors aware of the intervention received by study participants?	PN	0 EI reported.
	4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	NA	
	4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?	NA	
	Risk of bias judgement	Low	
Bias in selection of the reported result	5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	PY	No protocol has been published, but the announced method has been followed.
	5.2 ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	N	Effective alpha risk management (2 CDJs measured, but alpha firmly set at 0.1%).
	5.3 ... multiple eligible analyses of the data?	N	
	Risk of bias judgement	Low	
Overall bias	Risk of bias judgement	Low	



B. Mazières, *et al.* 2005

Domain	Signalling question	Response	Comments
Bias arising from the randomization process	1.1 Was the allocation sequence random?	Y	"computer generated global randomization code to receive either ketoprofen or placebo (in a 1/1 ratio) in blocks of 4 (2/2 ratio)"
	1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	Y	
	1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	N	Analysis of comparable characteristics in the two groups.
	Risk of bias judgement	Low	
Bias due to deviations from intended interventions	2.1. Were participants aware of their assigned intervention during the trial?	N	Blind. The number of EI cases was comparable in both groups
	2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?	N	
	2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the experimental context?	NA	
	2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?	NA	
	2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?	NA	
	2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	Y	ITT
	2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?	NA	
	Risk of bias judgement	Low	
Bias due to missing outcome data	3.1 Were data for this outcome available for all, or nearly all, participants randomized?	Y	Information provided about all data.
	3.2 If N/PN/NI to 3.1: Is there evidence that result was not biased by missing outcome data?	NA	
	3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?	NA	
	3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?	NA	
	Risk of bias judgement	Low	
Bias in measurement of the outcome	4.1 Was the method of measuring the outcome inappropriate?	N	EVA at J7
	4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	N	
	4.3 Were outcome assessors aware of the intervention received by study participants?	N	"no case of compromise blinding"
	4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	NA	
	4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?	NA	
	Risk of bias judgement	Low	
Bias in selection of the reported result	5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	PY	No protocol has been published, but the announced method has been followed.
	5.2 ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	N	Effective management of alpha risk (set at 5% and only one CJP).
	5.3 ... multiple eligible analyses of the data?	N	
	Risk of bias judgement	Low	
Overall bias	Risk of bias judgement	Low	

Domain	Signalling question	Response	Comments
Bias arising from the randomization process	1.1 Was the allocation sequence random?	PY	"randomization"
	1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	PY	
	1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	N	Analysis of comparable characteristics in the two groups.
	Risk of bias judgement	Low	
Bias due to deviations from intended interventions	2.1. Were participants aware of their assigned intervention during the trial?	PN	Blind.
	2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?	NI	.
	2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the experimental context?	PN	
	2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?	NA	
	2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?	NA	
	2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	PY	No patients lost to follow-up. Three patients were excluded after randomization because they did not meet the inclusion criteria = OK. ITT analysis.
	2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?	NA	
	Risk of bias judgement	Low	
Bias due to missing outcome data	3.1 Were data for this outcome available for all, or nearly all, participants randomized?	Y	Information provided about all data.
	3.2 If N/PN/NI to 3.1: Is there evidence that result was not biased by missing outcome data?	NA	
	3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?	NA	
	3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?	NA	
	Risk of bias judgement	Low	
Bias in measurement of the outcome	4.1 Was the method of measuring the outcome inappropriate?	N	EVA measurement on Day 7.
	4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	N	
	4.3 Were outcome assessors aware of the intervention received by study participants?	PN	Blind
	4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	NA	
	4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?	NA	
	Risk of bias judgement	Low	
Bias in selection of the reported result	5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	PY	No protocol has been published, but the announced method has been followed.
	5.2 ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	N	Effective management of alpha risk (set at 5% and 1 measured CDJ).
	5.3 ... multiple eligible analyses of the data?	N	
	Risk of bias judgement	Low	
Overall bias	Risk of bias judgement	Low	

R. Dreiser, et al. 1991

Domain	Signalling question	Response	Comments
Bias arising from the randomization process	1.1 Was the allocation sequence random?	PY	"randomization"
	1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	PY	
	1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	N	Analysis of comparable characteristics in the two groups.
	Risk of bias judgement	Low	
Bias due to deviations from intended interventions	2.1. Were participants aware of their assigned intervention during the trial?	PN	Blind
	2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?	NI	
	2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the experimental context?	PN	
	2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?	NA	
	2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?	NA	
	2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	PY	No patients lost to follow-up. Three patients were excluded after randomization because they did not meet the inclusion criteria = OK. ITT analysis.
	2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?	NA	
	Risk of bias judgement	Low	
Bias due to missing outcome data	3.1 Were data for this outcome available for all, or nearly all, participants randomized?	Y	Information provided about all data.
	3.2 If N/PN/NI to 3.1: Is there evidence that result was not biased by missing outcome data?	NA	
	3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?	NA	
	3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?	NA	
	Risk of bias judgement	Low	
Bias in measurement of the outcome	4.1 Was the method of measuring the outcome inappropriate?	N	EVA measurement on Day 7.
	4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	N	
	4.3 Were outcome assessors aware of the intervention received by study participants?	PN	Blind.
	4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	NA	
	4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?	NA	
	Risk of bias judgement	Low	
Bias in selection of the reported result	5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	PY	No protocol has been published, but the announced method has been followed.
	5.2 ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	N	Effective management of alpha risk (set at 5% and 1 measured CDJ).
	5.3 ... multiple eligible analyses of the data?	N	
	Risk of bias judgement	Low	
Overall bias	Risk of bias judgement	Low	

APPENDIX III - REB EVALUATION OF THE EFFICACY OF CERTAIN TOPICAL NSAIDS FOR PAIN ON MOVEMENT IN ACUTE TENDINOPATHIES

REB assessment of the efficacy of diclofenac epolamine in movement-related pain associated with acute tendinopathies														
Step 1:	At least 2 confirmatory RCTs					A single confirmatory RCT					No confirmatory RCTs			0 RCTs included
Number of conclusive RCTs														
Step 2:	Positive meta-analysis		Non-positive meta-analysis			Positive			Non-positive		Positive		Non-positive	NA
Results														
Step 3: Heterogeneity	N/N	Y/N	Y/Y	N/N	Y/N or Y/Y	N/N	Y/N	Y/Y	N/N	Y/N or Y/Y	N/N	Y/N or Y/Y	N/N or O/O or O/N	NA
and publication bias														
publication														
Interpretation	Strong evidence	Signal	No evidence	Signal	No evidence	Evidence to be confirmed	Report	No evidence	Report	No evidence	Signal	No evidence	No evidence	No evidence

REB assessment of the efficacy of ketoprofen in pain on movement associated with acute tendinopathies														
Step 1:	At least 2 confirmatory RCTs					A single confirmatory RCT					No confirmatory RCTs			0 RCTs included
Number of conclusive RCTs														
Step 2:	Positive meta-analysis		Non-positive meta-analysis			Positive			Non-positive		Positive		Non-positive	NA
Results														
Step 3: Heterogeneity	N/N	Y/N	Y/Y	N/N	Y/N or Y/Y	N/N	Y/N	Y/Y	N/N	Y/N or Y/Y	N/N	Y/N or Y/Y	N/N or O/O or O/N	NA
and publication bias														
publication														
Interpretation	Strong evidence	Signal	No evidence	Signal	No evidence	Evidence to be confirmed	Report	No evidence	Report	No evidence	Signal	No evidence	No evidence	No evidence

REB assessment of the efficacy of niflumic acid in movement-related pain associated with acute tendinopathies														
Step 1:	At least 2 confirmatory RCTs					A single confirmatory RCT					No confirmatory RCTs			0 RCTs included
Number of conclusive RCTs														
Step 2:	Positive meta-analysis		Non-positive meta-analysis			Positive			Non-positive		Positive		Non-positive	NA
Results														
Step 3: Heterogeneity	N/N	Y/N	Y/Y	N/N	Y/N or Y/Y	N/N	Y/N	Y/Y	N/N	Y/N or Y/Y	N/N	Y/N or Y/Y	N/N or O/O or O/N	NA
and publication bias														
publication														
Interpretation	Strong evidence	Signal	No evidence	Signal	No evidence	Evidence to be confirmed	Report	No evidence	Report	No evidence	Signal	No evidence	No evidence	No evidence

REB assessment of the efficacy of diclofenac in chronic tendinopathy pain

Step 1:	At least 2 confirmatory RCTs					A single confirmatory RCT					No confirmatory RCTs		0 RCTs included	
Number of conclusive RCTs														
Step 2:	Positive meta-analysis					Non-positive meta-analysis					Positive		Non-positive	
Results														
Step 3: Heterogeneity														
and publication bias	N/N	Y/N	Y/Y	N/N	Y/N or Y/Y	N/N	Y/N	Y/Y	N/N	Y/N or Y/Y	N/N	Y/N or Y/Y	N/N or O/O or O/N	NA
publication														
Interpretation	Strong evidence	Signal	No evidence	Signal	No evidence	Evidence to be confirmed	Report	No evidence	Report	No evidence	Signal	No evidence	No evidence	No evidence